GRANT & EISENHOFER P.A.
Jay W. Eisenhofer
Geoffrey C. Jarvis
Jeff A. Almeida
Deborah A. Elman
Robert D. Gerson
485 Lexington Avenue, 29th Floor
New York, NY 10017
Telephone: (646) 722-8500

SAIBER LLC
Jeffrey W. Lorell
Marc E. Wolin
18 Columbia Turnpike, Suite 200
Florham Park, NJ 07932
Telephone: (973) 622-3333

DIAZ REUS ROLFF & TARG LLP
Alexander Reus
340 West Flagler Street, Second Floor
Miami, FL 33130
Telephone: (786) 235-5000

Attorneys for Plaintiffs

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AEGON INVESTMENT MANAGEMENT B.V. ACTING JOINTLY WITH AEGON CUSTODY B.V., KUWAIT INVESTMENT OFFICE, THE LONDON OFFICE OF KUWAIT INVESTMENT AUTHORITY, AND THE KUWAIT INVESTMENT AUTHORITY ACTING ON BEHALF OF THE GOVERNMENT OF THE STATE OF KUWAIT, TRANSAMERICA FUNDS, TRANSAMERICA SERIES TRUST, and TRANSAMERICA PARTNERS PORTFOLIOS, Plaintiffs, v. MERCK & CO., INC., RAYMOND V. GILMARTIN, JUDY C. LEWENT, ALISE S. REICIN, KENNETH C. FRAZIER, EDWARD M. SCOLNICK, DAVID W. ANSTICE, and PETER S. KIM, Defendants.	Case No. _____ **JURY TRIAL DEMANDED**

TABLE OF CONTENTS

Plaintiffs AEGON Investment Management B.V., acting jointly with AEGON Custody B.V.; Kuwait Investment Office, the London Office of Kuwait Investment Authority, and the Kuwait Investment Authority acting on behalf of the Government of the State of Kuwait for the accounts of the Future Generation Fund and the Minister of Finance Fund; Transamerica Funds, Transameria Series Trust, and Transamerica Partners Portfolios, (collectively, "Plaintiffs"), by and through their attorneys Grant & Eisenhofer P.A and Diaz Reus Rolff & Targ LLP, allege the following upon information and belief, except as to those allegations concerning Plaintiffs, which are alleged upon personal knowledge. This action is brought against Merck & Co., Inc. ("Merck" or the "Company"), Raymond V. Gilmartin, Judy C. Lewent, Alise S. Reicin, Kenneth C. Frazier, Edward M. Scolnick, David W. Anstice, and Peter S. Kim (collectively, the "Individual Defendants") (together with Merck, the "Defendants"). Plaintiffs' information and belief is based upon, among other things, their investigations, conducted by and through their attorneys, into the facts and circumstances alleged herein including, without limitation: (a) review and analysis of certain filings made by Merck & Co., Inc. with the United States Securities and Exchange Commission ("SEC"); (b) review and analysis of certain press releases, public statements, news articles, medical studies, and other publications disseminated by or concerning the Defendants named herein and related parties; (c) review and analysis of certain Merck press conferences, analyst conference calls and conferences, and the corporate website of Merck; (d) review and analysis of securities analyst reports concerning Merck and its operations; (e) review and analysis of prepared statements and other sworn testimony given before the United States Senate Committee on Finance ("Senate Finance Committee") on November 18, 2004; (f) review and analysis of certain publicly-available trial exhibits from several product liability jury trials against Merck; and (g) review and analysis of certain other information,

documents, and materials concerning Merck and the other defendants named herein. Plaintiffs believe substantial, additional evidentiary support for their allegations will be obtained after a reasonable opportunity for discovery.[1]

I. SUMMARY OF THE ACTION

1. This action, which is for fraud, negligent misrepresentation, and conspiracy, involves what the United States Food and Drug Administration ("FDA") has called "the single greatest drug catastrophe in the history of this country or the history of the world."

2. For more than five years, from May 21, 1999 through October 2004, Defendants knew, recklessly disregarded, intentionally and consistently misrepresented, concealed, and/or failed to disclose the fact that one of Merck's most profitable prescription drug products, Vioxx, presented a statistically significant risk of serious adverse cardiovascular ("CV") reactions, including thrombotic events such as heart attack, stroke, and death, among the patients for whom prescriptions of Vioxx were dispensed and to whom the drug was marketed.

3. In his November 2004 testimony before the Senate Finance Committee, Dr. David Graham, an associate director with the FDA, estimated that Vioxx likely caused as many as

---

[1] In an August 8, 2011 opinion addressing Defendants' motions to dismiss, this Court, *inter alia*, dismissed, without prejudice, the class plaintiffs' claims under Section 10(b) of the Exchange Act against Gilmartin, Kim, Lewent, Frazier, and Anstice, and dismissed the class plaintiffs' claims to the extent they are based on alleged misstatements or omissions after September 29, 2004. *See In re Merck & Co. Sec., Derivative & "ERISA" Litig.*, MDL No. 1658 (SRC), 2011 U.S. Dist. LEXIS 87578, at *79-81, *103-06, *108-114 (D.N.J. Aug. 8, 2011). This Court also dismissed the class plaintiffs' claims under Section 20A of the Exchange Act against, among others, Gilmartin, Lewent, Frazier, and Anstice. Plaintiffs include those individuals as defendants in this case—asserting Section 10(b) and/or Section 20A claims against them—and include alleged acts from after September 29, 2004, to preserve all claims and rights. Additionally, in an August 29, 2012 opinion addressing Defendants' motion for judgment on the pleadings, this Court, *inter alia*, dismissed the class plaintiffs' claims under Section 20(a) of the Exchange Act against Gilmartin, Kim, Lewent, Frazier, and Anstice. *See In re Merck & Co. Sec., Derivative & "ERISA" Litig.*, MDL No. 1658 (SRC), 2012 U.S. Dist. LEXIS 123800, at *55-64 (D.N.J. Aug. 29, 2012). Plaintiffs include Section 20(a) claims against those defendants in this case to preserve all claims and rights.

100,000 people to suffer heart attacks, strokes, and/or death since the FDA approved Vioxx for prescription use as a pain-relief medication on May 21, 1999.

4. Merck was aware, even before the FDA approved Vioxx as a prescription drug on May 21, 1999, that Vioxx caused a statistically significant increase in cardiovascular and thrombotic events. Therefore, Merck knew that Vioxx was both a medical and commercial risk. Rather than withdraw Vioxx during the FDA approval process, Merck continued upon its ill-conceived course and obtained FDA approval of the drug. Thereafter, Defendants engaged in an aggressive marketing campaign -- driven by their materially false and misleading statements and/or omissions of material facts about the medical and commercial risks of Vioxx -- to boost Vioxx sales.

5. As a result of Merck's continual release of false and misleading information concerning the efficacy and safety of Vioxx, Merck's investors were led to believe that Vioxx was a financial blockbuster and would enhance Merck's business and financial performance for many years, while at the same time presenting minimal liability risks to the Company that would hinder its future financial performance. As is now known, Vioxx was a danger to the public and has created a material liability for Merck that could exceed $50 billion.

6. Merck's wrongful conduct assured, among other things, that: (i) Merck would reap substantial Vioxx-related revenues; (ii) Merck's stock price would be artificially inflated; and (iii) the Individual Defendants would receive enhanced revenue-related bonuses and other compensation and receive the proceeds of inflated stock sales.

7. On September 30, 2004, Merck finally acknowledged the dangers to Vioxx users that the Defendants had known for more than 5 years and withdrew Vioxx from the market. Merck's announcement that it was withdrawing Vioxx (the "September 30, 2004

Announcement") caused the Company's stock price and future earnings prospects to decline dramatically. As part of Merck's September 30, 2004 Announcement, the Company informed investors:

> The company currently expects earnings per share to be negatively affected by $0.50 to $0.60 as a result of today's announcement. This estimate includes foregone sales, writeoffs of inventory held by Merck, customer returns of product previously sold and costs to undertake the pullback of the product. Included in this cost estimate is the expectation of foregone fourth quarter sales of Vioxx of $700 million to $750 million. In addition, Merck expects that worldwide approximately one month of inventory is held by customers and will be returned.

Merck's stock price collapsed in reaction to the Company's September 30, 2004 Announcement. Merck common stock fell more than $12.70 to close at $33 per share -- a 26% single-day decline that reduced Merck's market capitalization by more than $26 billion. The $0.50 to $0.60 decrease in earnings per share that Merck announced on September 30, 2004, represents the loss of at least $1.1 billion in annual earnings.

8. Beginning with a press release issued May 21, 1999 (the first day of the Relevant Period), in which Merck trumpeted the news that the FDA had approved VIOXX for the treatment of osteoarthritis, and throughout the Relevant Period, Defendants engaged in an aggressive campaign to conceal both the medical and commercial risks associated with Vioxx. Virtually every time that any adverse information regarding Vioxx entered the marketplace, Merck immediately refuted such information and/or directly attacked the source of such information. Facts related to Merck's campaign of concealment continue to emerge, but much of what is now known was first set forth in a *Wall Street Journal* article dated November 1, 2004, the publication of which caused Merck's stock price to drop an additional $3.03, yielding a total Vioxx-related market capitalization decline of ***$37 billion***.

9. Plaintiffs purchased or otherwise acquired Merck securities between May 21, 1999 and October 29, 2004, inclusive (the "Relevant Period"). From November 6, 2003 until on or about November 1, 2013, Plaintiffs were members of the class in *In re Merck & Co., Inc. Securities Derivative & "ERISA" Litigation*, No. 2:05-cv-02367-SRC-CLW (D.N.J.) (the "Securities Class Action"), included in multidistrict proceedings (the "Merck-VIOXX MDL") pending before this Court (the "MDL Action").

10. By opinion of January 30, 2013, in accordance with Federal Rule of Civil Procedure 23, this Court certified the Securities Class Action as a class action on behalf of all persons and entities who, from May 21, 1999 to September 29, 2004, inclusive, purchased or otherwise acquired Merck common stock or call options, or sold Merck put options (the "Class"). *See In re Merck & Co. Sec. Derivative & ERISA Litig.*, MDL No. 1658 (SRC), 2013 U.S. Dist. LEXIS 13511 (D.N.J. Jan. 30, 2013). On November 1, 2013, in accordance with the procedures set forth in the Notice of Pendency of Class Action dated September 4, 2013, Plaintiffs submitted requests for exclusion from the Class. On December 3, 2013, a representative of the claims administrator in the Securities Class Action submitted an affidavit to the MDL Court affirming that Plaintiffs had timely requested exclusion from the Class. Having opted out of the Class, Plaintiffs now bring this suit to recover the significant losses they suffered due to the fraud Defendants perpetrated during the Relevant Period.

11. Plaintiffs have suffered millions of dollars in damages in connection with its purchases of Merck securities at artificially inflated prices and the subsequent drop in stock price as the direct result of Defendants' deliberate scheme to conceal, suppress and distort material facts throughout the Relevant Period concerning Vioxx's medical and commercial viability and the inevitable disclosure of the truth about Vioxx.

II. JURISDICTION AND VENUE

12. The claims of Plaintiffs alleged herein arise under §§ 10(b), 20(a) and 20A of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. §§ 78j(b) and 78t, and Rule 10b-5, 17 C.F.R. § 240.10b-5 promulgated thereunder by the SEC.

13. Jurisdiction is conferred by § 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. §§ 1331 and 1337.

14. Venue is proper in this District pursuant to § 27 of the Exchange Act and 28 U.S.C. § 1391(b). Merck is incorporated in New Jersey and its principal place of business and global headquarters are located in the District of New Jersey.

15. Defendants, in connection with the acts, transactions and conduct alleged herein, directly and indirectly, used the means and instrumentalities of interstate commerce, including, among others, interstate telephone communications, the United States mail, and the facilities of the national securities exchanges.

III. PARTIES

A. PLAINTIFFS

16. Plaintiff AEGON Investment Management B.V. ("AIM"), a wholly owned subsidiary of AEGON Asset Management Holding B.V., is a limited private company with limited liability (besloten vennootschap met beperkte aansprakelijkheid) incorporated and existing under the laws of the Netherlands. AIM has its seat at 's-Gravenhage, The Netherlands, and its registered place of business at AEGONplein 50, 2591 TV 's-Gravenhage, The Netherlands.

17. Plaintiff AEGON Custody B.V. (together with AIM, "AEGON"), a limited private company with limited liability (besloten vennootschap met beperkte aansprakelijkheid) incorporated and existing under the laws of the Netherlands has its seat at 's-Gravenhage, The

Netherlands, and its registered place of business at AEGONplein 50, 2591 TV 's-Gravenhage, the Netherlands. AEGON Custody B.V. appointed AIM to be its true and lawful attorney in fact.

18. Plaintiff the Kuwait Investment Office ("KIO") is the London office of Plaintiff Kuwait Investment Authority ("KIA"). Plaintiff KIO is located in the City of London, United Kingdom, and manages funds on behalf of the State of Kuwait. Plaintiff KIA's principal place of business is the State of Kuwait. KIA is an autonomous government body responsible for the management and administration of the General Reserve Fund, and the assets of the Future Generations Fund, as well as any other funds entrusted to it by the Minister of Finance for and on behalf of the State of Kuwait. Both KIO and KIA are acting for the economic interest of and represent the State of Kuwait, which is the overall beneficial owner of all the assets.

19. Plaintiff Transamerica Funds ("TF") is a statutory trust organized under the laws of the state of Delaware, USA. The principal place of business of TF is 570 Carillon Parkway, St. Petersburg, Florida 33716, USA. TF's registered office is Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801, USA.

20. Plaintiff Transamerica Series Trust ("TST") is a statutory trust organized under the laws of the state of Delaware, USA. The principal place of business of TST is 570 Carillon Parkway, St. Petersburg, Florida 33716, USA. TST's registered office is Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801, USA.

21. Plaintiff Transamerica Partners Portfolios ("TPP") is a trust organized under the laws of the state of New York, USA. The principal place of business and principal office of TPP is 570 Carillon Parkway, St. Petersburg, Florida 33716, USA. Prior to May 1, 2008, TPP was known as Diversified Investors Portfolios.

B. MERCK & CO., INC.

22. Defendant Merck & Co., Inc. is a global pharmaceutical company, incorporated in the state of New Jersey, which develops, manufactures and markets a broad range of health products. As of September 30, 2004, the Company had approximately 2.2 billion shares outstanding that traded on the New York Stock Exchange ("NYSE"). Merck is headquartered in New Jersey, with its principal place of business at One Merck Drive, Whitehouse Station, NJ 08889.

C. THE INDIVIDUAL DEFENDANTS

(i) Edward M. Scolnick

23. Defendant Edward Scolnick, M.D. ("Scolnick") served as President for Merck Research Laboratories and Merck's Executive Vice President of Science and Technology from the beginning of the Relevant Period until and including December 31, 2002. He performed research on Vioxx during that period and knew of its negative effects. From January 1, 2003 through the end of 2004, Scolnick served as President Emeritus, Merck Research Laboratories, performing research in the Company's Pennsylvania facilities.

24. Scolnick resides at 1201 Magnolia Drive, Wayland, Massachusetts 01778.

25. Scolnick signed the following documents which the Company filed with the SEC during the Relevant Period which contained materially false and misleading statements and/or omitted to state material facts: the 1998 Form 10-K; the May 3, 1999 Form S-3; the July 6, 1999 Form S-3A; the November 29, 1999 Form S-8; the February 16, 2000 Form S-8; the 1999 Form 10-K; the July 28, 2000 Form S-3; the November 28, 2000 Form S-8, the January 5, 2001 Form S-8; the February 27, 2001 Form S-8; the May 31, 2001 Form S-4; the 2001 Form 10-K; the April 23, 2002 Form S-3; and the November 27, 2002 Form S-8.

26. Scolnick was a direct, substantial, and primary participant in the misconduct detailed in this Complaint. While in possession of material adverse non-public information regarding Merck, Scolnick personally profited from the sale of his personal holdings of Merck securities at artificially inflated prices during the Relevant Period. During the Relevant Period, Scolnick sold 381,200 shares of Merck stock, recognizing more than $24.8 million in insider-trading profits. Additionally, from the beginning of the Relevant Period through his retirement, Scolnick received substantial revenue-based bonuses and other compensation that was artificially increased by the wrongful conduct set forth herein. From January 1, 2003 through the end of the Relevant Period, Scolnick was no longer subject to public reporting requirements concerning the sale of Merck stock. Without the benefit of further discovery, Plaintiffs are unable to ascertain whether Scolnick sold any additional shares of his personal holdings of Merck common stock during the Relevant Period.

(ii) Alise S. Reicin

27. Defendant Alise S. Reicin, M.D. ("Reicin") was the Executive Director of Clinical Research at Merck Research Laboratories during the Relevant Period. Reicin was responsible for researching the safety and efficacy of Merck products, including Vioxx. Reicin also wrote articles in defense of Merck products, including Vioxx, during the Relevant Period.

28. Reicin was a member of Merck's Management Committee, a senior management group which evaluated and made strategic decisions for the Company.

29. Reicin resides at 156 East Hamilton Avenue, Englewood, New Jersey 07631.

30. Reicin was a direct and substantial participant in the fraud who received substantial revenue-based bonuses and other compensation during the Relevant Period that was artificially increased by the wrongful conduct set forth herein.

31. As detailed herein, Reicin made numerous public statements concerning Vioxx during the Relevant Period that were materially false and misleading and/or omitted material facts concerning the continuing threat to Vioxx's medical and commercial viability posed by the severe cardiovascular and thrombotic risks that Vioxx presented.

(iii) Raymond V. Gilmartin

32. Defendant Raymond V. Gilmartin ("Gilmartin") was Merck's Chairman, President and Chief Executive Officer beginning in November 1994 and throughout the Relevant Period until May 5, 2005, when he "voluntarily resigned" (although he was not due to retire until March 2006). Gilmartin was Chairperson of Merck's Executive Committee, whose purpose was to act for the Board of Directors in the event that action was required between Board meetings. Gilmartin was also a member of Merck's Management Committee. The Management Committee and the Board of Directors shaped the Company's strategy and policies concerning financial performance, use of company assets, and all other vital business issues.

33. Gilmartin resides at 7739 SE Loblolly Bay Drive, Hobe Sound, Florida 33455.

34. Gilmartin signed the following documents that the Company filed with the SEC during the Relevant Period which concealed materially false and misleading statements and/or omitted to state material facts: the 1998 Form 10-K; the May 3, 1999 Form S-3; the July 6, 1999 Form S-3A; the November 23, 1999 Form S-8; the February 16, 2000 Form S-8; the 1999 Form 10-K; the March 16, 2000 Form S-8; the May 22, 2000 Form S-8; the July 28, 2000 Form S-3; the November 28, 2000 Form S-8; the January 5, 2001 Form S-8; the 2000 Form 10-K; the February 27, 2001 Form S-8; the May 31, 2001 Form S-4; the March 21, 2002 Form 10-K; the November 27, 2002 Form S-8; the April 23, 2002 Form S-3; the Second Quarter 2002 Form 10-Q; the Third Quarter 2002 Form 10-Q; the 2002 Form 10-K; the First Quarter 2003 Form 10-Q; the August 22, 2003 Form S-8; the September 23, 2003 Form S-8; the Third Quarter 2003

Form10-Q; the First Quarter 2004 Form 10-Q; the 2003 Form 10-K; the July 27, 2004 Form S-8; the Second Quarter 2004 Form 10-Q; the August 12, 2004 Form S-3; and the Third Quarter 2004 Form 10-Q.

35. Gilmartin was a direct, substantial, and primary participant in the misconduct detailed in this Complaint. While in possession of material adverse non-public information regarding Merck, Gilmartin personally profited from the sale of his personal holdings of Merck securities at artificially inflated prices during the Relevant Period. During the Relevant Period, Gilmartin sold 639,200 shares of Merck stock, recognizing more than $20.9 million in insider-trading profits. Additionally, during the Relevant Period, Gilmartin received substantial performance-based bonuses and other compensation based on, among other things, growth in Merck's earnings per share, Merck's sales compared to certain of Merck's competitors, and the change in the Company's return on operating assets versus the prior year.

(iv) Judy C. Lewent

36. Defendant Judy C. Lewent ("Lewent") was Merck's Senior Vice President and Chief Financial Officer and held the same positions during the Relevant Period. Lewent was responsible for, among other things, financial and corporate development functions, internal auditing, corporate licensing, and the Company's joint venture relationships. She joined Merck in 1980 as Director of Acquisitions and Capital Analysis. She was the Company's Chief Financial Officer for seventeen years, from 1990 until her retirement in August 2007.

37. Lewent resides at 141 Stone Fence Road, Bernardsville, New Jersey 07924.

38. Lewent signed the following documents that the Company filed with the SEC during the Relevant Period which contained materially false and misleading statements and/or omitted to state material facts: the 1998 Form 10-K; the May 3, 1999 Form S-3; the July 6, 1999 Form S-3A; the November 29, 1999 Form S-8; the February 16, 2000 Form S-8; the 1999 Form

10-K; the March 6, 2000 Form S-8; the May 22, 2000 Form S-8; the July 28, 2000 Form S-3; the November 28, 2000 Form S-8; the January 5, 2001 Form S-8; the 2000 Form 10-K; the February 27, 2001 Form S-8; the May 31, 2001 Form S-4; the 2001 Form 10-K; the November 26, 2002 Form S-8; the April 23, 2002 Form S-3; the Second Quarter 2002 Form 10-Q; the Third Quarter 2002 Form 10-Q; the 2002 Form 10-K; the First Quarter 2003 Form 10-Q; the August 22, 2003 Form S-8; the September 23, 2003 Form S-8; the Third Quarter 2003 Form 10-Q; the First Quarter 2004 Form 10-Q; the 2003 Form 10-K; the July 27, 2004 Form S-8; the Second Quarter 2004 Form 10-Q; the August 12, 2004 Form S-3; and the Third Quarter 2004 Form 10Q.

39. Defendant Lewent was a direct, substantial, and primary participant in the misconduct detailed in this Complaint. While in possession of material adverse non-public information regarding Merck, Lewent personally profited from the sale of her personal holdings of Merck securities at artificially inflated prices during the Relevant Period. During the Relevant Period, Lewent sold 267,200 shares of Merck stock, recognizing more than $11.1 million in insider-trading profits. Additionally, according to Merck's Relevant Period SEC filings, Lewent received substantial performance-based bonuses and other compensation based on, among other things, changes in Merck's earnings per share and sales compared to Merck's competitors.

(v) Kenneth C. Frazier

40. Defendant Kenneth C. Frazier ("Frazier") was Merck's Senior Vice President and General Counsel during the Relevant Period and held these positions since December 1999. On August 1, 2007, Frazier was promoted to Executive Vice President, Global Human Healthcare, the number two position at Merck, second only to Merck's current Chairman, President and CEO, Richard T. Clark. Frazier was responsible for legal and public affairs functions during the Relevant Period.

41. Frazier resides at 22 Weatherfield Drive, Newtown, Pennsylvania 18940.

42. Frazier signed the following documents that the Company filed with the SEC during the Relevant Period which contained materially false and misleading statements and/or omitted to state material facts: the First Quarter 2000 Form 10-Q; the Second Quarter 2000 Form 10-Q; the Third Quarter 2000 Form 10-Q; the First Quarter 2001 Form 10-Q; the Second Quarter 2001 Form 10-Q; the Third Quarter 2001 Form 10-Q; the First Quarter 2002 Form 10-Q; the Second Quarter 2002 Form 10-Q; the Third Quarter 2002 Form 10-Q; the First Quarter 2003 Form 10-Q; the Second Quarter 2003 Form 10-Q; the Third Quarter 2003 Form 10-Q; the First Quarter 2004 Form 10-Q; the Second Quarter 2004 Form 10-Q; and the Third Quarter 2004 Form 10-Q.

43. Frazier was a direct, substantial, and primary participant in the misconduct detailed in this Complaint. While in possession of material adverse non-public information regarding Merck, Frazier personally profited from the sale of his personal holdings of Merck securities at artificially inflated prices during the Relevant Period. During the Relevant Period, Frazier sold 38,960 shares of Merck stock, recognizing more than $1.2 million in insider-trading profits.

(vi) David W. Anstice

44. Defendant David W. Anstice ("Anstice") was, at all relevant times, President of Merck's Human Health Prescription Division, which made him privy to information regarding the safety of Vioxx. Anstice was a member of Merck's Management Committee, a senior management group which evaluates and makes strategic decisions for the Company. Anstice has been with Merck since 1972.

45. Anstice resides at 5280 Militia Hill Road, Plymouth Meeting, Pennsylvania 19462-1217.

46. Anstice was a direct, substantial, and primary participant in the misconduct detailed in this Complaint. While in possession of material adverse non-public information regarding Merck, Anstice personally profited from the sale of his personal holdings of Merck securities at artificially inflated prices during the Relevant Period. Anstice sold 432,019 shares of Merck stock from his personal holdings, recognizing more than $20.8 in insider-trading profits. Additionally, during the Relevant Period, Anstice received substantial revenue-based bonuses and other compensation that was artificially increased by the wrongful conduct set forth herein.

(vii) Peter S. Kim

47. Defendant Peter S. Kim, M.D. ("Kim") replaced Scolnick as President of Merck Research Laboratories on January 1, 2003, and held that position throughout the remainder of the Relevant Period. Kim joined the Company and became an executive officer in February 2001. Kim is a member of Merck's Management Committee, a senior management group which evaluates and makes strategic decisions for the Company.

48. Kim resides at 450 Boxwood Road, Bryn Mawr, Pennsylvania 19010.

49. Kim was a direct and substantial participant in the fraud who received substantial revenue-based bonuses and other compensation during the Relevant Period that was artificially increased by the wrongful conduct set forth herein.

IV. SUMMARY OF DEFENDANTS' FRAUDULENT SCHEME

50. Throughout the Relevant Period, Merck and Defendants Gilmartin, Lewent, Reicin, Frazier, Scolnick, Anstice, and Kim (the "Individual Defendants") (collectively, the "Defendants" or the "Merck Defendants") deliberately pursued a fraudulent scheme to make false and misleading statements and to omit disclosing material facts concerning Vioxx's safety and medical and commercial viability. During this time, the Defendants possessed, but failed to

disclose, statistically significant data demonstrating that Vioxx posed high cardiovascular and thrombotic risk that threatened Vioxx's medical and commercial viability. Many of the details of Defendants' fraud have emerged following the Company's September 30, 2004 Announcement. The significant risk of cardiovascular or thrombotic events due to Vioxx known to the Defendants but concealed by the Defendants until on or after September 30, 2004 include sudden cardiac death, heart attack, unstable angina, transient ischemic attack, thrombosis, arterial blood clots and venous blood clots.

A. THE DEVELOPMENT OF VIOXX AND THE DRUG'S VALUE TO MERCK

51. Conditions such as arthritis and spinal disorders and injuries cause chronic pain. Prior to 1999, persons suffering chronic pain and inflammation turned to certain non-steroidal anti-inflammatory drugs ("NSAIDs"), such as aspirin, ibuprofen, and naproxen for relief. People taking NSAIDs over a protracted time period, however, often developed stomach ulcers and other gastrointestinal ("GI") problems.

52. NSAIDs effectively block two enzymes: Cyclooxygenase 1 and Cyclooxygenase 2 ("COX-1" and "COX-2," respectively). COX-1 is an enzyme that protects the stomach's lining. COX-2 is an enzyme that causes pain and inflammation. Traditional NSAIDS, such as ibuprofen and naproxen, suppress the pain-causing enzyme COX-2, but also suppress COX-1, thereby causing harmful gastrointestinal side effects. Vioxx, which is generically named rofecoxib, was developed as a "COX-2 inhibitor" that would provide the pain-relieving qualities of traditional NSAIDs without the negative gastrointestinal side-effects.

53. The potential market for a successful COX-2 inhibitor like Vioxx was huge. Even for people who do not have pre-existing stomach or GI problems, using NSAIDs like aspirin, ibuprofen or naproxen over a protracted period of time presents a risk of harmful gastrointestinal side effects.

54. Merck's financial success and future prospects depended on Vioxx becoming a "blockbuster" drug. Within the five to seven years after Vioxx's expected arrival on the market in mid-1999, Merck would be facing patent expiration dates for several of its best-selling drugs and the resulting loss of at least $4 billion in annual revenues to generic competition. For example, the patent for Zocor, Merck's blockbuster cholesterol reduction medication that accounted for $4.5 billion in sales in 1999, and $5.3 billion in 2000, was set to expire in 2006. Other profitable Merck drugs scheduled to lose patent protection during the Relevant Period included Vasotec, a blood-pressure medication that accounted for over $2.3 billion in sales in 1999, and Pepcid, which accounted for $910 million in revenues in 1999 and $850 million in 2000.

55. Merck needed Vioxx to make up for these soon-to-be-lost sales. Drug-industry analyst Michael Krensavage at Raymond James & Associates was quoted in a *New York Times* article entitled "Despite Warnings, Drug Giant Took Long Path to Vioxx Recall," "***Vioxx was Merck's savior, it's as simple as that***." (Emphasis added).

56. Until the truth about Vioxx was disclosed and Vioxx was withdrawn from the market, Vioxx was extremely profitable for Merck and extremely expensive for consumers. To the end-user, Vioxx cost $100 to $134 a month, compared with $18.19 a month for prescription naproxen, or $7.50 per month for over-the-counter naproxen. (The dose for over-the-counter naproxen is slightly lower than that for prescription naproxen).

57. By the end of the 1990's, in order to turn Vioxx into the blockbuster it needed, Merck had to ensure that Vioxx would be quickly available. Two of Merck's competitors -- Pfizer, Inc. ("Pfizer") and Monsanto Co. ("Monsanto") -- had jointly developed and received approval to market Celebrex, another COX-2 inhibitor. In an April 14, 1999 article, *The Wall*

Street Journal reported that Celebrex had already become "one of the most successful new drugs in industry history."

58. The competitive effect of Celebrex on Vioxx sales was a constant motivation for Merck to distort and suppress the truth about Vioxx during the Relevant Period. Merck had already seen sales of its earlier-developed cholesterol drug, Zocor, lag significantly behind Pfizer's Lipitor. Merck did not want to suffer another such defeat. Indeed, in the spring of 1999, industry analysts knew that Vioxx and Celebrex were about to face off in battle. At that time, analyst Hemant Shah stated that "to be able to displace Celebrex," Vioxx would have to show "significant superiority" in its labeling, such as an enhanced safety profile.

59. Dr. Alan S. Nies, now retired, was Merck's scientist leading the Vioxx development program in the 1990's. The Defendants, along with Dr. Nies, tried to rush federal approval for Vioxx because they feared that Celebrex, Pfizer's competing drug, would get approval first.

60. At the time the Company announced it had filed its approval application with the FDA, Merck stated its internal studies showed Vioxx did not cause negative gastrointestinal side effects. As set forth below, however, Defendants already knew, but failed to disclose, that notwithstanding any gastrointestinal benefits it might have, Vioxx dangerously increased the risk that patients would suffer severe and possibly deadly cardiovascular and thrombotic events, including but not limited to myocardial infarctions.

61. Merck had come under substantial pressure from Wall Street for moving too slowly to expand its pharmaceuticals pipeline, which was an additional reason that Vioxx's success was critical to Merck.

B. "STUDY 090" AND OTHER PRE-FDA APPROVAL INDICATORS OF VIOXX'S DANGERS

62. Even before Merck received FDA approval to market Vioxx (which occurred on May 21, 1999), the Company was aware that Vioxx presented a statistically significant risk of serious cardiovascular and thrombotic side effects. Internal company documents demonstrate that Merck personnel actively sought to conceal Vioxx's damaging effects as early as 1996.

63. According to a November 1, 2004 article in *The Wall Street Journal*, a memo that a Merck official authored on November 21, 1996, expressed a fear that proposed clinical tests designed to demonstrate that Vioxx did not negatively impact the human gastrointestinal system had a "substantial chance [of showing] significantly higher rates" of cardiovascular complications and thrombotic events than other drugs.

64. This fear was reiterated in 1997, when a Merck official, Briggs Morrison, warned that testing Vioxx on patients who did not simultaneously take aspirin would highlight "***more thrombotic events" -- that is, blood clots – "and kill [the] drug."*** (Emphasis added). Morrison recognized the fact that the blood-thinning characteristics of aspirin would, at least theoretically, mitigate the significant risk of cardiovascular and thrombotic events that Merck even then associated with Vioxx.

65. Responding to this fear, Merck's then Vice President for Clinical Research, Defendant Reicin, wrote an e-mail stating that Merck was in a "no-win situation." Dr. Reicin agreed that "***the possibility of increased CV [cardiovascular] events is of great concern.***" (Emphasis added). In the same email, Dr. Reicin suggested "excluding high risk CV patients" in order to "***decrease the CV event rate so that a difference between the two groups would not be evident***." (Emphasis added.)

66. Dr. Eric Topol ("Dr. Topol"), Chief of Cardiovascular Medicine at the Cleveland Clinic, presented information concerning Defendants' early knowledge of the dangers of Vioxx on the November 14, 2004 edition of CBS's 60 Minutes. According to Dr. Topol, a never-published 1998 internal Merck clinical trial entitled "Study 090," revealed that of the 978 participating patients serious cardiovascular and thrombotic events -- including heart attack and stroke -- resulted six (6) times more frequently in patients taking Vioxx than in patients taking a different arthritis drug or placebo. Merck never disclosed either the adverse findings of Study 090 or the fact that those findings were independently replicated by a larger, later study, known as VIOXX Gastrointestinal Outcomes Research ("VIGOR"), in early 2000.

67. As early as May 1998, the Vioxx "Project Team," headed by Defendant Scolnick, collected data on cardiovascular events in all Vioxx clinical trials, including, *inter alia*, myocardial infarction, stroke, transient ischemic attack, and angina. Even as early as May 1998, Merck and the members of the Vioxx Project Team, including Scolnick, were aware that Vioxx could disturb endothelium-platelet interaction to favor platelet aggregation and thus cause significantly increased cardiovascular risk due to Vioxx.

68. On April 20, 1999, Merck official Beth Seidenberg presented the FDA's Arthritis Advisory Committee ("AAC") with the Company's interpretation of certain clinical results that Merck offered in support of Vioxx's marketing approval. Among other things, Seidenberg stated that certain clinical trials that Merck had conducted on persons with osteoarthritis demonstrated that Vioxx was statistically superior to a placebo and equally effective as ibuprofen in reducing pain.

69. Later during the same presentation to the AAC, Merck spokesperson Thomas Simon commented upon a clinical study that, according to Simon, demonstrated that patients

taking Vioxx were less likely to suffer stomach ulcers than patients taking ibuprofen. In this regard, Simon represented that Vioxx was "superior" to ibuprofen.

70. At no point during the presentation to the FDA's AAC did Merck representatives mention that Merck's internal studies, including Study 090, demonstrated that Vioxx presented a heightened risk of heart attacks and other cardiovascular events. Without the benefit of this information, the AAC voted to recommend Vioxx for treating osteoarthritis and other sources of chronic pain.

71. While Merck was aware of the significant cardiovascular and thrombotic dangers that Vioxx presented, the Defendants did not disclose these risks and did not take steps to ensure Vioxx's safety. Instead, the Defendants actively concealed this information and continued to press for FDA approval. Merck's primary goal -- apparently without regard to the human or economic cost -- was to get Vioxx to market as quickly as possible so that it could successfully compete with Celebrex.

C. THE FDA APPROVES VIOXX FOR PRESCRIPTION USE

72. Merck submitted its New Drug Application for Vioxx to the FDA on or about November 23, 1998. On or about January 11, 1999, Merck issued a press release claiming that the Company's application for approval included the results of sixty-eight (68) studies involving nearly 10,000 patients.

73. On May 21, 1999 -- the first day of the Relevant Period -- the FDA approved Vioxx for prescription use as a pain management medication for persons with osteoarthritis, for women suffering from menstrual pain, and for adults with certain other acute pain-causing conditions. The same day, a story appearing on the Dow Jones Newswire encapsulated the importance of Vioxx's success to Merck: "The battle for this summer's blockbuster may not occur in movie theaters, but instead in the corner drugstore."

74. The article was referring, of course, to the battle between Vioxx and Celebrex for COX-2 inhibitor supremacy. Celebrex, which was approved in January 1999, had been on the market for several months before Vioxx and doctors had written 4.4 million prescriptions for Celebrex since its approval. Celebrex was second only to Viagra as the fastest-selling drug in history. By the third quarter of 1999, Celebrex would surpass Viagra as the most successful drug launch in pharmaceutical history.

75. On May 21, 1999, Merck issued a press release announcing that the FDA had approved Vioxx. Although Merck stated that taking Vioxx may cause diarrhea, nausea, and upper respiratory infection, the Company knowingly failed to disclose the significant risk of severe cardiovascular and thrombotic events.

D. THE VIGOR STUDY INDEPENDENTLY REPLICATES STUDY 090'S FINDINGS OF VIOXX'S SEVERE CARDIOVASCULAR AND THROMBOTIC RISKS, BUT DEFENDANTS NEVERTHELESS CONTINUE TO DELIBERATELY CONCEAL THE MEDICAL AND COMMERCIAL RISKS

76. In January 1999, prior to the FDA's approval of Vioxx and the beginning of the Relevant Period, Merck commenced the Vioxx Gastrointestinal Outcomes Research ("VIGOR") study of approximately 8,100 rheumatoid arthritis patients in order to determine whether Vioxx reduced the risk of serious gastrointestinal side effects associated with other NSAIDs. The VIGOR study compared the results of patients taking Vioxx (50 mg) to those taking naproxen (1000 mg).

77. In March 2000, less than one year after the FDA's approval of Vioxx, the VIGOR study results were available to Merck. While the results indicated that Vioxx reduced the risk of gastrointestinal side effects, they also revealed that the Vioxx patients were ***five times more likely to suffer a heart attack*** than those taking naproxen. The VIGOR study's findings

regarding the significant negative cardiovascular and thrombotic impacts of Vioxx were buried by Merck for the next four years.

78. Importantly, the VIGOR results independently replicated the results of Study 090. The significance of this independent replication of the harm that could be caused to Vioxx users was confirmed by Dr. Eric Topol, the Chief of Cardiology at the Cleveland Clinic. Dr. Topol told 60 Minutes (in a show broadcast on November 14, 2004) that:

> Merck took on any study that questioned the safety of Vioxx with respect to the heart attacks and strokes. Any study. … Whenever you find a problem and you're thinking maybe it's not a problem, you want to see if there's independent replication. So if you have Study 090 and you want to discount that somehow, then you have VIGOR. You've got two trials now. You have essentially lightning striking twice. That's independent replication. That's really serious confirmation. This is unequivocal. This is a problem.

79. On March 9, 2000, Defendant Scolnick, then Merck's Chief of Research, sent an e-mail to Merck executives stating that the VIGOR results showed that cardiovascular and thrombotic events "***are clearly there***." Acknowledging that Vioxx was at fault, Scolnick stated: "it is a shame but it is a low incidence and ***it is mechanism-based as we worried it was***." "Mechanism-based" means the thrombotic and cardiovascular problems related to Vioxx's molecular structure. The e-mail also stated that Defendant Scolnick wanted to develop all available data before Merck made the VIGOR results public, in order to attempt to show that the cardiac and thrombotic risks were an effect of all COX-2 inhibitors, not just Vioxx. As discussed further herein, for the next four years Merck made no public mention of Dr. Scolnick's conclusion that Vioxx itself was increasing the risk of cardiac and thrombotic events.

80. Indeed, in December 2001, as Merck prepared for its annual meeting with analysts and reporters, Dr. Scolnick got furious about a Wall Street analyst's negative report on

Vioxx safety. "[I]f he says this I will boil him in oil at the meeting," Dr. Scolnick wrote to a colleague.

81. When Merck did make the results of the VIGOR study public in early 2000, it did so in a misleading manner. The Company deliberately obscured the true significance of VIGOR, stating that it was confirming "the favorable cardiovascular profile of Vioxx . . . in response to speculative news reports."

82. These statements were bolstered by a Merck public statement on April 28, 2000, designed to quell potential negative reaction toward Vioxx arising from the VIGOR study. In this regard, the Company stated:

> Extensive review of data from the completed osteoarthritis trials and on-going clinical trial with Vioxx, as well as post-marketing experience with Vioxx, have shown no difference in the incidence of cardiovascular events, such as heart attack, among patients taking Vioxx, other NSAIDs and placebo.

83. In all of their public statements concerning the VIGOR study, Merck and the Individual Defendants consistently misrepresented the results of the study. Rather than concede that Vioxx presented a significant risk of serious cardiovascular and thrombotic events, Defendants, on those occasions when they addressed the issue at all, claimed the imbalance in the results was attributable to the "cardioprotective properties of naproxen" (the "Naproxen Hypothesis") -- an argument that was unproven, entirely speculative, and indeed contradicted by Merck's own internal research. In addition, as the internal emails and other documents made public in the wake of the Vioxx fallout reveal, Merck and the Individual Defendants never believed in good faith in this argument, but always knowingly or recklessly used it as subterfuge to deflect inquiries concerning Vioxx's cardiovascular safety profile.

E. THE "NAPROXEN HYPOTHESIS"

84. As stated above, on March 9, 2000, after Defendant Scolnick saw internal VIGOR results, Scolnick wrote "it [the increased cardiovascular risk of Vioxx] is mechanism based as we knew it would be." Eighteen days later Merck issued a press release, dated March 27, 2000, touting the VIGOR study results and saying the cardiovascular risks of Vioxx were consistent with naproxen acting like aspirin. Under the false "Naproxen Hypothesis," Merck argued to the FDA and others that Vioxx did not increase cardiovascular risk compared to naproxen (contrary to its own internal data). Instead, Merck and the other Defendants came up with a knowingly false hypothesis to suit their purposes – that Vioxx did not increase cardiovascular risk, instead naproxen must be "cardio-protective." The "Naproxen Hypothesis" advanced by Merck and the other Defendants was knowingly false when made.

85. Scolnick's internal March 9, 2000 email, when contrasted with the Merck March 27, 2000 press release, demonstrates Defendants' fraud on investors. When compared side-by-side, they show that, in only 18 days, Merck, Scolnick and other Defendants magically transformed their position on the cardiovascular risks of Vioxx from being "clearly there" and "mechanism based as we knew it would be" to unqualified support for the false "Naproxen Hypothesis:" an unsubstantiated theory that naproxen is aspirin-like in cardio-protective qualities and hence, an alleged basis for the Defendants to claim Vioxx does not cause statistically significantly increased cardiovascular risk.

86. There was no credible, reliable, or published clinical trial anywhere in the world showing naproxen with such powerful cardioprotective tendencies (naproxen had existed since 1976). What the Merck Defendants claimed in the March 27, 2000 press release, was either intentionally false as Plaintiffs allege, or at a minimum wholly reckless; a "shot in the dark" theory without any basis.

87. In a desperate effort to identify any scientific basis for the "Naproxen Hypothesis," senior Merck scientists, including Defendants Scolnick and Reicin, searched for prior studies that support the baseless theory that naproxen is cardioprotective. Although they worked at this well into the nights following March 9, 2000, the search was in vain. At 1:20am on March 13, 2000, Defendant Reicin emailed Defendant Scolnick and Dr. Alan S. Nies with the results of the search:

> Alan and Ed:
>
> Below is attached the abstract for the ***only study*** I could find which assessed the potential cardioprotective effects of an NSAID.
>
> Alise

The abstract Defendant Reicin attached was for a 1993 article in the *European Heart Journal*. That article discussed the use of flurbiprofen, a traditional NSAID, versus placebo administered in patients within six hours of suffering a heart attack. The study was small (464 patients) and had absolutely no relation to naproxen. The article speculated that flurbiprofen may offer advantages over aspirin, stressing that further research is necessary. Since naproxen was not used in the study, the article offered no claims about naproxen's safety or efficacy profile.

88. This failure to unearth any scientific basis for the "Naproxen Hypothesis" did not dampen Merck's lead scientists' vigor. A March 24, 2000 email from Dr. Garret FitzGerald (an external consultant who conducted Vioxx study Protocol 023) to Dr. Nies (the Merck scientist who led the development of Vioxx) furnished the latter with what Dr. FitzGerald called "the best comparative clin[ical] data on MI [myocardial infarction] and NSAIDs" of which he was aware. On the same day, Dr. Nies forwarded this email and this data to Defendant Reicin and Dr. Barry Gertz, another senior Merck scientist.

89. The data provided by Dr. FitzGerald was from an unpublished study involving 164,000 patients. The data was organized to present specific data about the possible cardioprotective effects of aspirin, naproxen, ibuprofen, and diclofenac individually and in certain combinations. Although the data showed that aspirin may significantly reduce the risk of suffering a first, nonfatal heart attack, the other NSAIDs, ***including naproxen***, "had no significant effect" – whether individually or in combination – on the risk of suffering a heart attack. This email and the data it contained therefore not only failed to provide Merck and the Individual Defendants with the scientific support they so desperately needed, but actually subverted the claim that naproxen is cardioprotective.

90. These data were not disclosed to the market. Although Dr. FitzGerald's email to Dr. Nies contained individualized data about the efficacy of each of the different NSAIDs, the published version, which appeared in *Epidemiology* in July 2000, contained only **aggregate** figures. In addition, the article refers only to non-aspirin traditional NSAIDs rather than naming naproxen explicitly. Dr. FitzGerald's email suggests that he acquired the disaggregated data from the study authors directly. Merck was thus in possession of non-public scientific data on naproxen that directly refuted their "Naproxen Hypothesis," which nevertheless continued to make appearances in Merck's statements to the market concerning Vioxx.

91. In any event, the manner in which the March 27, 2000 press release is written ("consistent with naproxen's ability to block platelet aggregation") grossly misled the investing public as to any scientifically known benefits of naproxen. Merck and the other Defendants had access to, or were themselves, some of the brightest and most sophisticated scientists in all of medical science. The Defendants knew that naproxen was not capable of producing any such

platelet-blocking ability or cardio-protective effect. Their claims to the contrary, including claims representing their good-faith belief in the "Naproxen Hypothesis," were fraudulent.

F. MERCK HIDES FROM THE FDA PROTOCOL 906 RESULTS WHICH DEMONSTRATED STATISTICALLY SIGNIFICANT INCREASED RISK OF EDEMA AND HYPERTENSION

92. Internal documents not disclosed to the public until 2007 show a statistically significant higher risk of hypertension and edema from Vioxx versus Pfizer's Celebrex. These results were demonstrated in a Merck internal study called "Protocol 906."

93. Protocol 906 was a four-week study that compared the safety and efficacy of rofecoxib 25mg (Vioxx) and celecoxib 200mg (Celebrex) in the treatment of osteoarthritis of the knee and hip. *See* July 23, 2001 Memorandum "Preliminary Statistical Analysis of CDSP MK-966, Protocol 906-01" from W. Malbecq to A. Moan and M. Gabriel at MRK-NJ0199451 [MRK-NJ0199451-455] ("A preliminary statistical analysis is currently being performed for MK-966, Protocol 906-01, an active comparator-controlled, parallel-group, 4-week, double-blind study, conducted under in-house blinding procedures, to further evaluate the safety and tolerability and to compare the clinical efficacy of rofecoxib vs. celebrex in the treatment of osteoarthritis of the knee and hip . . . the study was intended to show that rofecoxib 25 mg is superior to celecoxib 200 mg in reducing pain at night . . ."). The study was conducted in the first half of 2001.

94. Protocol 906 revealed that "the proportion of patients with any type of edema was significantly higher after treatment with rofecoxib;" the results also revealed that the Vioxx patients had a higher rate, *inter alia*, of adverse experiences, drug related adverse experiences, discontinuations due to adverse experiences, hypertension adverse experiences and drug related hypertension adverse experiences. *See* July 23, 2001 Memorandum "Preliminary Statistical Analysis of CDSP MK-966, Protocol 906-01," at MRK-NJ0199452-3.

95. On May 18, 2001, while in the process of reviewing Merck's supplemental NDA that included the VIGOR data, the FDA sent instructions to Merck regarding an upcoming submission of safety data. *See* May 18, 2001 fax from Sandra Folkendt to Robert Silverman, MD (MRK-AAF0003971-72). The FDA specifically requested that the upcoming submission include:

(i) All ongoing and completed studies of rofecoxib;

(ii) Analyses of cardiovascular events for each individual study; and

(iii) Where the studies included comparison of Vioxx to another NSAID, analyses and comparisons of Vioxx to each of those individual NSAIDs.

Id.

96. On May 25, 2001, Merck replied to the FDA's request, but proposed leaving out information from six completed short-term studies, including Protocol 906, explaining that the requested studies would provide only "minimal information." *See* May 25, 2001 Letter from Robert Silverman to Jonca Bull at MRK-AAF0003987 (MRK-AAF0003986-88).[2]

97. Internal e-mails, however, indicate that Merck scientists questioned whether Protocol 906 provided only "minimal" information, and, in fact, called the results "very serious," and stressed the need for the results to be kept "VERY TIGHT." *See* July 23, 2001 e-mail from Vandormael to Gabriel and Moan (MRK-NJ0199459-460) (emphasis in original).

98. Merck did keep this data "very tight," so tight, in fact, that it withheld the Protocol 906 results regarding the statistically significant increased risk of edema with Vioxx compared to Celebrex, and the increased risk of hypertension with Vioxx compared to Celebrex from the FDA, submitting only limited Protocol 906 data. *See* July 30, 2001 Response to FDA

[2] Just three days earlier on May 22, 2001, Merck issued a press release that "reconfirmed the favorable cardiovascular safety of Vioxx." *See* Press Release "Merck Confirms Favorable Cardiovascular Safety Profile of Vioxx," (MRK-ABI0003228-30) (May 22, 2001).

Request for Information Safety Update Report at MRK-0120159578 (MRK-0120159554-83). The result of Merck's reluctance to share its data is that the FDA never received the hypertension data from Protocol 906, and this data was never reflected in any iteration of the Vioxx label. Thus, Merck failed to provide the FDA with all relevant information prior to the approval of the post-VIGOR labeling.

G. THE "ADVANTAGE" CLINICAL TRIAL WARNS MERCK OF THE NEGATIVE CARDIOVASCULAR EFFECTS OF VIOXX, BUT THE DEFENDANTS CHOOSE TO COVER UP THOSE NEGATIVE EFFECTS

99. In the late 1990's, Merck conducted a small (5,500 patients), 8-week clinical trial of Vioxx known as the "Advantage Trial" through which it hoped to demonstrate the gastrointestinal benefits of Vioxx. Merck's marketing department had created the Advantage trial as a promotional tool, to introduce about 600 doctors to Vioxx.

100. According to an article published by *The New York Times* on April 24, 2005, entitled "Evidence in Vioxx Suits Shows Intervention by Merck Officials," (the "April 24, 2005 *New York Times* article") undertaking this small clinical trial was itself controversial at Merck, because it essentially duplicated the larger, VIGOR trial that was then underway. In an e-mail, Defendant Scolnick wrote, "This course is just stupid." He further noted that: "Small marketing studies which are intellectually redundant are extremely dangerous." In e-mail messages on April 7, 2001, to Dr. Douglas A. Greene, an executive vice president at Merck Research Laboratories, Dr. Scolnick wrote that he was especially angry because the Advantage trial had no scientific purpose.

101. The Advantage trial was completed in 2000, but its results were not published until 2003, when they appeared in the Annals of Internal Medicine, a well-regarded journal.

102. In the published study, Dr. Jeffrey R. Lisse, a rheumatologist at the University of Arizona, who is listed as the study's first author, reported that five patients taking Vioxx had suffered heart attacks during the trial, compared with one taking naproxen.

103. Dr. Lisse told *The New York Times* that, while he was listed as the paper's first author, Merck actually wrote the report, an unusual practice. "Merck designed the trial, paid for the trial, ran the trial," Dr. Lisse said. "Merck came to me after the study was completed and said, 'We want your help to work on the paper.' The initial paper was written at Merck, and then it was sent to me for editing."

104. The reason for the delay in the publication of the trial results is now clear – Merck changed the data to suit its purposes. During the Advantage trial, eight people taking Vioxx suffered heart attacks or sudden cardiac death, compared with just one taking naproxen, according to data released by the FDA in 2005. The difference was statistically significant, but Merck never disclosed the data that way. Instead, as noted above, they disclosed only five cardiac-related deaths.

105. According to the April 24, 2005, *The New York Times* article, in 2000, Merck overruled one of its own scientists after he suggested that a patient in the Advantage trial had probably died of a heart attack.

106. This "controversial meddling" (as reported by the *New York Times*) concerned the death of a 73-year-old, female participant in the trial. The 73-year-old woman died on October 21, 1999, a few minutes after calling her son to tell him she felt short of breath. By the time her son reached her house, she was dead. According to the April 24, 2005 *New York Times* article, records show that she had been taking 25 milligrams of Vioxx a day as part of the clinical trial.

107. According to the April 24, 2005 *New York Times* article, after Merck reviewed the case internally, Dr. Eliav Barr, a Merck scientist, initially judged that the woman had probably died of a heart attack. "Common things being common, the clinical scenario is likely to be MI," Dr. Barr wrote in an e-mail message in November 2000 to Defendant Reicin, the clinical research executive. ("MI" is an abbreviation for myocardial infarction, or heart attack.) "Certainly, it is not definitive. I just used my clinical judgment."

108. Defendant Reicin quickly responded, "I think this should be called an unknown cause of death." A few hours later, Reicin wrote, "I would prefer unknown cause of death so we don't raise concerns."

109. In one e-mail message, Defendant Scolnick said the drug trial that included the woman's death had "put us in a terrible situation." Defendant Scolnick expressed his worry in e-mail messages to other senior Merck scientists that the Advantage results would encourage the FDA to demand that Vioxx's label highlight its significant cardiac and thrombotic risks. Such a change would have damaged Vioxx's sales, especially because Merck's COX-2 competition, Pfizer's Celebrex, did not have heart risks prominently displayed on its warning label.

110. According to the April 24, 2005 *New York Times* article, when Merck presented the data from the Advantage trial to the FDA, it classified the woman's death as unknown. But in November 2001, an FDA reviewer who had examined all the company's data concluded in a report to other agency officials that Merck had misclassified the death and should have referred the case to an outside committee.

111. Moreover, when Dr. Lisse, the author of the 2003 paper on the Advantage study was told of the manipulation of the cause of the 73-year-old woman's death, he said he had never

heard of the case of the woman who died. He stated that "[b]asically, I went with the cardiovascular data that was presented to me."

H. UNDISCLOSED DATA FROM TWO MERCK STUDIES INVOLVING ALZHEIMER'S PATIENTS DEMONSTRATE THAT VIOXX INCREASES THE RISK OF CARDIAC MORTALITY

112. Data from two further studies carried out by Merck revealed the cardiovascular risks of Vioxx. That data became available to Merck in April 2001 but was not disclosed to the market. The two studies (Protocol 078 and Protocol 091) examined the relationship of Vioxx to the onset and progression of Alzheimer's disease. The studies failed to demonstrate any benefit of Vioxx in relation to these endpoints, and revealed that Vioxx was associated with significantly higher mortality rates, including deaths from heart disease.

113. Protocols 078 and 091 were modeled on the theory that inflammatory mechanisms aggravated by COX-2 enzymes were associated with Alzheimer's disease. Treatment with a selective COX-2 inhibitor like Vioxx might alleviate this inflammation and thus prevent or retard the development of Alzheimer's disease, according to the hypothesis at the base of the trials.

114. The mortality data from these studies was available internally on or around April 8, 2001. On that date, Dr. Joshua Chen, a Merck statistician, prepared an internal memorandum summarizing the mortality data from Protocols 078 and 091. This memorandum did not become public until after the Relevant Period. It discloses a ***statistically significant increased risk of mortality in all patients taking Vioxx*** compared to all patients taking placebo in both trials. Protocol 078 showed twenty-one deaths in patients taking Vioxx versus nine deaths in patients taking placebo: this is a statistically significant increase in risk of death of 257%. Protocol 091 showed thirteen deaths in patients taking Vioxx versus three deaths in patients taking placebo: this is a statistically significant increase in risk of death of 467%. Combined, these studies

showed a statistically significant increase in risk of death of 287% in patients taking Vioxx versus those taking placebo.

115. Despite this evidence of Vioxx's increased risk of cardiac mortality, which Merck possessed since April 2001, the "Naproxen Hypothesis" remained the official story and this data was not released to the public. Merck even provided inaccurate data concerning Protocols 078 and 091 to the FDA. In July 2001, Merck filed a Safety Update Report with the FDA that misrepresented the mortality data from these studies by inventing a new, post-hoc definition of "mortality events" that obscured Vioxx's risks. Using this new definition, Merck was able to report to the FDA substantially reduced, non-statistically significant increased risks of mortality. An October 31, 2001 internal memorandum makes clear that this new definition was not used until the time at which Merck had to report data on Protocols 078 and 091 to the FDA approached.

116. On the basis of this new definition of "mortality event," Merck reported to the FDA that fifteen Vioxx patients had died in Protocol 078 as compared to nine placebo patients. This represents a non-statistically significant increase in risk of death of 187%. Merck also reported to the FDA that fourteen Vioxx patients had died in Protocol 078 as compared to eight placebo patients. This represents a non-statistically significant increase in risk of death of 209%. Merck made to the FDA the materially false and misleading misrepresentation that "review of the deaths does not identify a specific increased risk with rofecoxib" and that Vioxx's profile for serious adverse clinical events was "generally similar to that of placebo." This effort to obscure Vioxx's cardiovascular and mortality risks, including the misrepresentations to the FDA, constitute a part of Merck's and the Individual Defendants' fraudulent scheme to withhold the truth about Vioxx from investors.

I. THE FDA WARNS MERCK THAT THE COMPANY'S VIOXX PROMOTIONAL MATERIALS ARE FALSE AND MISLEADING

117. The FDA sent Defendants a letter on December 16, 1999 (the "December 16, 1999 FDA Letter"), stating that Merck's promotional materials for Vioxx were "false or misleading because they contain misrepresentations of Vioxx's safety profile, unsubstantiated comparative claims, and are lacking in fair balance." The letter stated that Merck's claim that compared to Celebrex, Vioxx was stronger, lasted longer, worked faster, and was safer "suggest[ed] Vioxx is more efficacious and has a superior safety profile compared to Celebrex, when such has not been demonstrated by substantial evidence. Therefore, this unsubstantiated comparative claim is misleading."

118. The December 16, 1999 FDA Letter, which Merck neither disclosed to the public or apparently even responded to, also expressed disapproval of the balance of information that the Company was presenting regarding Vioxx. In particular, the FDA cited Merck's minimization of Vioxx's risks as inappropriate:

> Although these pieces contain numerous claims for the efficacy and safety of Vioxx, you have not presented <u>any</u> risk information concerning the contraindications, warnings, precautions, or adverse events associated with Vioxx's use. Therefore, we consider these promotional pieces to be lacking in fair balance. Furthermore, these promotional pieces are in violation of the Act because the approved product labeling for Vioxx did not accompany them.

J. MERCK'S UNWAVERING CAMPAIGN TO SILENCE VIOXX'S CRITICS

(i) Merck Suppresses Negative Information About Vioxx

119. Despite the Company's awareness of mounting evidence showing the dangers of heart attack and stroke associated with Vioxx, Merck actively suppressed information where possible, refused to engage in or fund studies of the correlation between Vioxx, on the one hand, and cardiac and/or thrombotic incidents, on the other hand, and instead embarked upon a vast

marketing campaign to discredit the evidence and promote Vioxx sales. During the Relevant Period, the Company and the Individual Defendants -- all members of Merck's top level management -- engaged in a continuous and con campaign to reassure consumers that Vioxx was safe and to inform investors that Vioxx's medical and commercial viability was not in jeopardy. The Defendants consistently took substantial steps to dissipate any notion that Vioxx presented a significant risk of cardiovascular and thrombotic problems.

120. Merck deliberately hid any adverse information concerning Vioxx. If anyone contradicted Merck's rosy picture of Vioxx, Merck would try to discredit such statements by, among other things, issuing its own positive statements about Vioxx's benefits. These statements were materially false and misleading and/or omitted to state material facts.

121. For example, on April 28, 2000, Merck issued a press release entitled "Merck confirms favorable cardiovascular safety profile of Vioxx," in which the Company acknowledged the VIGOR trial results, but stated that other trials showed no difference in the incidence of cardiac events between Vioxx and a placebo, or between Vioxx and traditional NSAIDs. The April 28, 2000 Press Release directly contradicted Study 090 and Merck's internal conclusions, including the Scolnick e-mail, that Vioxx caused significantly increased cardiovascular and thrombotic risks.

122. In November 2000, VIGOR results were published in the *New England Journal of Medicine* by academics retained by Merck. The November 2000 article touted Vioxx's benefits for the stomach. The Merck-retained academics reported that Vioxx did not show a significant rise in heart attacks and did not provide detailed information about other serious cardiovascular complications such as strokes or blood clots.

(ii) Merck "Gags" The Medical Community To Prevent The Public From Knowing About Vioxx's Dangers

123. Merck officials exerted extreme pressure on members of the medical community who expressed negative opinions about Vioxx's safety in an attempt to downplay the drug's risks. For example, Stanford University medical professor Dr. James Fries said that Dr. Louis Sherwood, a high-ranking Merck official, tried to intimidate doctors expressing concerns about Vioxx's safety, and made charges to their superiors that the doctors were biased against Vioxx. According to the November 1, 2004 *Wall Street Journal* article, Fries wrote a complaint letter to Merck after he received a call from Dr. Sherwood, who warned him that Stanford University professor, Dr. Gurkirpal Singh, would "flame out" unless he ceased giving "anti-Merck" lectures. Fries stated that after he learned the phone call was part of a pattern, he wrote to Defendant Gilmartin to protest Merck's attempt to suppress academic discussions. A CBSNews.com article dated November 5, 2004, entitled "Merck Faces Slew of Vioxx Suits," quotes Fries as stating: "I think Merck went over the line. *Their approach was to try to get people fired for saying things [Merck] didn't agree with."* (Emphasis added).

124. According to the November 1, 2004 *Wall Street Journal* article, Dr. M. Thomas Stillman, a professor at the University of Minnesota, discussed data linking Vioxx to high blood pressure and swelling in his Merck-sponsored lectures. Shortly thereafter, Dr. Stillman received a call from Merck's Dr. Sherwood. Dr. Stillman stated: "We had a very direct conversation that I wouldn't call friendly. It had to me a tone of 'You better be careful of what you're saying.'" Dr. Stillman stopped giving Merck-sponsored lectures after the phone call.

125. The *Wall Street Journal* further reported that Dr. Lee S. Simon, a rheumatologist and associate chief of medicine at Beth Israel Deaconess Medical Center in Boston, who was involved with research on Pfizer's competitor drug Celebrex, stated he had worked with Merck

in another area. Dr. Simon said that after he publicly mentioned data showing that Vioxx might be associated with risks of high blood pressure and swelling, both he and his superiors at the hospital received calls from Dr. Sherwood, complaining that Dr. Simon's lectures were biased against Vioxx. Dr. Simon is quoted as stating: "I was shocked that there was a phone call made like that. The company was attempting to suppress a discussion about this data."

126. When behind-the-scenes pressure was not enough, Merck would make the attacks public and personal. For example, Merck denounced Dr. Wayne A. Ray, Professor of Preventive Medicine at the Vanderbilt University School of Medicine, and a study he did at Vanderbilt in which Dr. Ray found high doses of Vioxx led to heart attacks**.** Merck attacked both Dr. Ray and his methodology. Merck argued Dr. Ray only conducted an epidemiological study, examining patient records for a correlation between Vioxx and cardiac incidents, but did not conduct a clinical trial. Merck's attacks suggested that Merck had actual clinical trial data refuting Dr. Ray's conclusions -- data Merck never produced and did not possess.

127. Merck attempted to silence Vioxx critics abroad as well. For example, in the Summer of 2002, Dr. Joan-Ramon Laporte, editor of the journal for the Catalan Institute of Pharmacology in Barcelona, Spain, published criticisms of Merck's handling of Vioxx. After the criticisms were published, Merck officials sent Dr. Laporte a "rectification" for publication, which Dr. Laporte declined to publish. Merck thereafter sued Dr. Laporte and the Catalan Institute in Spain, demanding a public correction of allegedly inaccurate published information. Two years of litigation later, in January 2004, the Spanish court ruled that Dr. Laporte's publication accurately reflected the debate over Vioxx's safety, and ordered Merck to pay court costs. During the pendency of its litigation with the Catalan Institute, Merck made no effort to disclose the truth about Vioxx or to make Vioxx safer.

128. Even while pursuing litigation, Merck also sought to harm Dr. Laporte personally and professionally. Dr. Laporte had been a speaker at a Merck-sponsored annual pharmaceutical meeting for 1,000 Spanish family physicians every year since 1998. After Dr. Laporte criticized Vioxx, Merck told the meeting's organizer that it would prefer if Dr. Laporte did not speak at the program, even though he had been a featured speaker at previous meetings. After the meeting organizer rejected the request to remove Dr. Laporte, Merck withdrew its financing of approximately $140,000 from the meeting. Dr. Ramon Morera i Castell, the meeting organizer, said Merck's message in withdrawing its funding was clear -- the Company would not tolerate any criticism of Vioxx.

(iii) Merck Refuses To Fund Direct Studies Of Cardiovascular Risks Associated With Vioxx

129. In May 2000, the Defendants met to discuss ways to defend Merck against the idea that Vioxx posed cardiac and thrombotic risks. The Defendants considered whether to finance the development of a cardiac risk study, but could not agree how or whether a trial could be performed. Defendants decided not to pursue any study to directly test what Merck already knew from Study 090 and VIGOR -- that Vioxx caused increased cardiovascular and thrombotic risks. Meeting documents show Merck marketing executives were among those most strenuously opposed to financing a cardiovascular and thrombotic risk study. Those same marketing executives instead launched a $500 million advertising and promotional campaign aimed at hiding the truth about Vioxx's significant cardiovascular and thrombotic risks. Merck hired Dorothy Hamill for print ads and for the incessant broadcasting of Vioxx television commercials set to the tune of The Rascals' 1968 hit "It's a Beautiful Morning."

130. In order to avoid the problems that would be presented by a study to directly test the risks of Vioxx, Defendants decided to monitor and manipulate trials being conducted for

other purposes that were either already under way or planned for the future. For example, Merck expanded and manipulated the Adenomatous Polyp Prevention on Vioxx ("APPROVe") trial -- a clinical study of Vioxx started in early 2000 to determine whether Vioxx could prevent the recurrence of colon polyps. Defendants' manipulations delayed final resolution of the APPROVe trial by several years. In the end, the results of the APPROVe clinical trial (made public by Merck in September 2004) did nothing more than confirm what Merck had known since 1998: that Vioxx caused a significant risk of cardiovascular and thrombotic events.

K. MERCK TOOK STEPS TO "NEUTRALIZE" DOCTORS WHO TOOK A NEGATIVE VIEW OF VIOXX

131. On February 11, 2005, *The New York Times*, in an article entitled "Marketing of Vioxx: How Merck Played Game of Catch-Up," reported on how Defendants sought to "neutralize" physicians who either supported Celebrex over Vioxx or took a negative view of Vioxx:

> Drug companies routinely try to woo doctors to prescribe or promote their drugs, taking them out to fancy meals, hiring them as speakers, or contributing to medical schools. ***But [] internal Merck documents offer a rare, behind-the-scenes look into the extremes of this process – one that may have blurred the line between legitimate promotion and offering inducements to doctors to prescribe a drug***.

(Emphasis added).

132. The article elaborated on the internal Company documents:

> The New York Times obtained the documents cited in this article -- records that include email messages, memorandums and spreadsheets -- through a public official. ***Some of those records involved physicians Merck sought to "neutralize," while others described promotional activities aimed at doctors not on that list.***

(Emphasis added).

133. *The New York Times* article described how Defendants attempted to neutralize physicians whom Defendants believed had a negative view of Vioxx:

> In the "neutralize" documents written by a Merck marketing executive, company officials identified dozens of influential but "problem" physicians whom the company believed had either a negative view of Merck or Vioxx or were active boosters of Celebrex.
>
> To win them over, the documents show, Merck officials planned to offer them carrots like clinical trials, posts as consultants or give them grants.
>
> "Attached is the complete list of 36 physicians to neutralize with background information and recommended tactics," the marketing official wrote in an e-mail message [dated July 23, 1999].
>
> Merck officials insisted that all the activities they financed were "educational." But one part of a standardized form requesting payments to doctors had a somewhat less erudite tone. It read "Expected Outcome/Return on Investment."

134. The physicians Merck targeted to "neutralize" were influential in their communities, were high prescribers, and had been favoring painkillers other than Vioxx. Among the recommended plans to "neutralize" the physicians was to offer one of the physicians a "weekend consults' meeting in an elegant location (New York, Hawaii) or a 5-day International Meeting with the top thought leaders on pain management."

L. MERCK TRAINS COMPANY SALES PERSONNEL TO "DODGE" QUESTIONS CONCERNING VIOXX'S CARDIOVASCULAR AND THROMBOTIC RISKS

135. On November 1, 2004, *The Wall Street Journal* published an article reporting that an internal Merck training document allegedly instructed sales representatives to "dodge" certain questions that the Company anticipated doctors would ask regarding the safety of Vioxx. A Merck internal marketing document, issued to Vioxx sales personnel in 2000 (the "Dodge Ball Memo"), purported to provide its recipients with an "obstacle handling guide." Among other things, the Dodge Ball Memo posed hypothetical doctors' statements including: "I am

concerned about the cardiovascular effects of Vioxx" and "[t]he competition has been in my office telling me that the incidence of heart attacks is greater with Vioxx than Celebrex." Merck's terse answer to each of the foregoing questions was the same: "DODGE!" Merck sales representatives were trained to view any doctor's questions about Vioxx heart risk as an "obstacle" to be avoided or dismissed.

136. In the episode of 60 Minutes broadcast on November 14, 2004, a Merck sales representative detailed the meaning of "DODGE!" in the above-described circumstances:

> We were supposed to tell the physician that Vioxx did not cause cardiovascular events, that, instead, in the studies, Naproxen has aspirin-like characteristics which made Naproxen -- a heart-protecting type of drug, where Vioxx did not have that heart-protecting side. . . . I put my reputation on the line. I gave my physicians my word that Vioxx was a safe, effective product, and it's been pulled from the market because it was killing people.

137. The British medical journal *The Lancet* published a comment online on November 5, 2004, discussing the Dodge Ball Memo. The doctors who authored *The Lancet* article concluded that information in the Dodge Ball Memo indicated that Merck management was well-aware of Vioxx's risks by at least 2000. *The Lancet* commented: "Given this disturbing contradiction -- Merck's own understanding of Vioxx's true risk profile and its attempt to gloss over these risks in their public statements at the time -- it is hard to see how Merck's chief executive officer, Raymond Gilmartin, can retain the confidence of the public, his company's most important constituency."

M. THE APPROVE TRIAL CONFIRMS WHAT MERCK HAD KNOWN AND ACTIVELY CONCEALED SINCE BEFORE MAY 1999 -- VIOXX POSED AN UNACCEPTABLY HIGH RISK OF HEART ATTACK AND OTHER CARDIOVASCULAR PROBLEMS

138. The APPROVe study, begun in early 2000, was designed to be a three-year study to determine whether Vioxx could help prevent the recurrence of colon polyps. Merck expanded the APPROVe study to include a number of other objections, expanded significantly the number

of patients and relevant clinical observations, and changed certain methodologies. The APPROVe study, which was originally to have been completed in early 2003, still had several months to run when it was terminated in September 2004. The study was halted upon the recommendation of the Chairperson of the APPROVe trial steering committee because of the clear emerging evidence of significant cardiovascular and thrombotic risk. Of course, the cardiovascular and thrombotic risks that APPROVe highlighted had been well-known to the Defendants since 1998.

139. Almost six years after learning of the medical and commercial risks associated with Vioxx, Merck finally disclosed Vioxx's cardiovascular and thrombotic problems and withdrew Vioxx from the market on September 30, 2004.

V. THE TRUTH ABOUT VIOXX IS REVEALED TO THE PUBLIC

A. MERCK'S SEPTEMBER 30, 2004 ANNOUNCEMENT

140. On September 30, 2004, Merck withdrew Vioxx from the market after years of denying that it presented a public health hazard, and citing what it misleadingly called "new evidence" (the discontinued APPROVe study) that Vioxx increased the risk of heart attacks and strokes. The FDA subsequently issued a Public Health Advisory to Vioxx users, informing them of the withdrawal and advising patients to consult with their physicians about alternative medications.

141. Following the withdrawal, Merck announced it would take a charge of $700 to $750 million in the second half of 2004 to cover Vioxx withdrawal expenses. Merck also retracted its third-quarter profit forecast and cut its full-year earnings estimate by 50 to 60 cents per share. The estimated costs to the Company included foregone sales, write-offs of inventory, customer returns of previously sold Vioxx prescriptions and costs to implement the withdrawal of Vioxx.

142. In reaction to the Company's September 30, 2004 Announcement, Merck's stock price collapsed. By the close of trading on September 30, 2004, the Company's stock price had fallen by more than $12 per share: representing a loss of more than $26 billion in market capitalization. The news shocked the financial market. David Moskowitz, an analyst with Friedman, Billings & Ramsey correctly concluded: "*This is nothing short of a disaster*."

143. The September 30, 2004 Announcement was only the beginning. On November 1, 2004, *The Wall Street Journal* revealed the truth behind Merck's campaign of concealment, making it clear Merck knew about the medical and commercial risks of Vioxx before it was approved by the FDA in May 1999. On learning of this news, the market lost all confidence in the truthfulness, integrity and leadership of Merck's management as well as the accuracy of Merck's financial statements and the share price declined by an additional 10% ($3.03) per share. Overall, Merck shareholders saw the market capitalization of the Company decline by a total of $37 billion upon the disclosure of Merck's Vioxx-related fraud.

B. FURTHER NEWS OF MERCK'S SUPPRESSION OF INFORMATION CONCERNING VIOXX'S RISKS EMERGES

144. Following the withdrawal of Vioxx, news emerged concerning certain studies, conducted during the Relevant Period, which indicated that Vioxx was unsafe. In each case, Merck had previously publicly attacked the results, methodology and/or person or group conducting the study, thereby wholly undercutting the credibility of the clinicians involved and their conclusions.

(i) The FDA/Kaiser Permanente Study

145. In August 2004, Dr. David Graham, a researcher for the FDA, concluded an epidemiological study based on data from 1.4 million patients in the Kaiser Permanente health care system. Dr. Graham found that: (1) high doses of Vioxx increased the risk of heart disease

by 3.7 times; (2) Vioxx was associated with more than 27,000 heart attacks or deaths linked to cardiac problems; and (3) persons taking Vioxx were 50% more likely to suffer severe cardiovascular problems than those taking Celebrex. Even in mid-September 2004 -- a mere two weeks before Vioxx was pulled from the markets -- Merck vehemently disagreed with Dr. Graham's conclusions.

146. In a November 10, 2004 *Wall Street Journal* article, entitled "Did FDA Staff Minimize Vioxx's Red Flags?", Dr. Graham was quoted as concluding in a draft study e-mailed to a supervisor on August 11, 2004, "[h]igher-dose rofecoxib [VIOXX] should not be prescribed or used." After FDA officials questioned the appropriateness of drawing strong conclusions about the higher dose rofecoxib, on August 13, 2004, Dr. Graham reworked his earlier conclusion, stating: "'[t]his and other studies cast serious doubt on the safety of rofecoxib' at doses greater than 25 milligrams a day." Declining to use weaker and more suggestive language, "Dr. Graham wrote that he had 'gone as far as he could without compromising' his conclusions." The *Wall Street Journal* quoted Dr. Graham as stating: "I wasn't trying to be obstinate, but I had an honest conclusion that history and the scientific evidence have proven to be correct."

147. When Merck withdrew Vioxx on September 30, 2004, the Company falsely stated that it had acted responsibly by voluntarily withdrawing the drug as soon as it had clear evidence that the drug was harmful. Merck simply lied. It had done all it could to avoid reporting the significant cardiovascular and thrombotic risks of Vioxx, despite becoming aware of such risks well before it obtained FDA approval for the drug.

(ii) The November 5, 2004 Lancet Article

148. A study published in the November 5, 2004 online edition of the British medical journal *The Lancet*, entitled "Risk of Cardiovascular Events and Rofecoxib: Cumulative Meta-analysis" (the "Lancet study") addressed the results obtained by a team of researchers led by Dr.

Peter Juni of the University of Bern. Dr. Juni's team observed 18 randomized controlled trials and 11 observational studies, finding that the "cumulative meta-analysis of randomized controlled trials indicates that an increased risk of myocardial infarction was evident from 2000 onwards." According to Dr. Juni, "at the end of 2000, the effect was both substantial and unlikely to be a chance finding."

149. The researchers found little evidence that the relative risk depended on the control group (those patients taking placebos, naproxen or other traditional NSAIDs). Rather, the observational studies revealed that "the cardioprotective effect of naproxen was small … and could not have explained the findings of the VIGOR trial."

150. The Lancet study concluded that Vioxx should have been withdrawn years earlier, when Merck clearly became aware of the risks of cardiac and thrombotic events. According to an article in NewScientist.com dated November 5, 2004, Matthias Egger, who co-authored the Lancet study, stated: "If we can do this kind of analysis, it's difficult to see why it wasn't done by the drug company or the licensing authorities years ago."

(iii) The Vanderbilt University Letter

151. Following the withdrawal of Vioxx, news emerged that in 1999, Dr. John Oates, a Vanderbilt University pharmacology professor, wrote to Merck's top scientist, Defendant Scolnick. In the letter, Professor Oates described four patients who had heart attacks or strokes while taking a Cox-2 inhibitor. Merck never publicly disclosed the problems revealed to it by Dr. Oates.

(iv) The UnitedHealth Group Study

152. According to *The New York Times* November 18, 2004 article, a study conducted by Merck officials and Dr. Alexander Walker, an executive of UnitedHealth Group, determined

that Vioxx posed an increased risk of cardiovascular problems, compared with the other drugs studied. This study was never made public by Merck.

(v) Merck Battled The FDA On Vioxx's Safety

153. Following the withdrawal of Vioxx, news emerged concerning an internal email dated February 8, 2001, in which Defendant Scolnick, then President of Merck Research Laboratories, stated his antipathy towards FDA pressure on Merck to put safety warnings on Merck's blockbuster drug, Vioxx. Fearful that an FDA warning would hurt sales, Merck fought the FDA. In the February 8, 2001 email, Scolnick wrote to his Vioxx development team after a Merck presentation to the FDA advisory committee: "You made them look like grade D high school students." When a Merck employee called the FDA's proposed warning "ugly" in an email, Scolnick responded: "It is ugly cubed. They are bastards."

(vi) Merck Lied To The Medical Community Concerning Vioxx's Safety

154. Also following the withdrawal of Vioxx, news emerged concerning a July 19, 2001 letter to doctors in which Merck seriously understated the heart risks faced by patients taking Vioxx. In the letter, Merck reported that of patients taking Vioxx in the largest clinical trial of the drug ever, only 0.5 percent had incurred "cardiovascular events," or heart and circulation problems. That would mean only about 20 patients among the more than 4,000 who took Vioxx during the study. But in fact, 14.6 percent of the patients – or 590 people – had cardiovascular troubles while taking the drug, according to Merck's own report on the study to federal regulators. And 2.5 percent, or 101 people, had serious problems, like heart attacks. Merck sent the letter to thousands of doctors. The 0.5 percent figure that Merck mentioned in the letter to doctors was false because the 0.5 figure referred to the risk of *heart attacks* faced by patients taking Vioxx in the trial, not the total risk of cardiovascular problems generally.

(vii) Merck Failed To Disclose The Negative Results Of Alzheimer's Studies On Vioxx's Safety

155. Subsequent to the withdrawal of Vioxx, Defendant Scolnick, former president of Merck Research Laboratories, admitted that Alzheimer's disease patients who took Vioxx in two studies had higher death rates than those on a placebo, but Merck never notified physicians or its sales representatives. Scolnick admitted that Merck should have told doctors prescribing Vioxx about the data in 2001.

156. The two Alzheimer's studies, involving about 2,000 patients, were done to determine whether Vioxx could delay the onset or worsening of the neurological disorder. In one study, 13 people taking Vioxx died, compared with three taking a dummy pill; in the other, 21 Vioxx takers died, versus nine on placebo.

157. Scolnick has testified he did not know whether the data was given to the FDA and admitted no letter was sent to physicians and that data about deaths among Alzheimer's patients was not added to the information card Merck salespeople used to answer doctors' questions. Nor did Merck ever issue a news release or seek to publish the data about the Alzheimer's studies.

(viii) News Emerges Concerning Merck Internal Emails Demonstrating Merck's Undisclosed Concerns About Vioxx's Safety

158. Also following the withdrawal of Vioxx, news emerged concerning numerous Merck internal e-mails demonstrating Merck had undisclosed concerns about Vioxx's safety. A November 21, 1996 memo by a Merck official shows the Company wrestling with this issue. Merck wanted to conduct a trial to prove Vioxx was gentler on the stomach than older painkillers. But to show the difference most clearly, the Vioxx patients could not take any aspirin. In such a trial, "there is a substantial chance that significantly higher rates" of cardiovascular problems would be seen in the Vioxx group, the memo said. A similar view was expressed in a February 25, 1997 e-mail by a Merck official, Briggs Morrison. He argued that

unless patients in the Vioxx group also got aspirin, ***"you will get more thrombotic events"*** -- that is, blood clots -- ***"and kill [the] drug."*** (Emphasis added.) In response, Defendant Reicin, then a Merck vice president for clinical research, said in an e-mail that the Company was in a "no-win situation." Giving study subjects both Vioxx and aspirin, she wrote, could increase the "relative risk," apparently referring to gastrointestinal problems. But, she added, "The possibility of increased CV [cardiovascular] events is of great concern." Her suggestion for countering this dilemma was to "exclud[e] high risk CV patients" in order to "***decrease the CV event rate so that a difference between the two groups would not be evident***." (Emphasis added.)

C. MERCK FACES A WAVE OF VIOXX-RELATED LITIGATION

159. On May 23, 2005, Judge Eldon E. Fallon of the U.S. District Court, Eastern District of Louisiana, reportedly told attorneys in his courtroom in New Orleans that Merck could ultimately face 100,000 personal injury cases over Vioxx.

160. Analyst Richard Evans of Sanford C. Bernstein Research estimated that Merck's Vioxx-related legal costs could exceed $12 billion. Early estimates from Merrill Lynch indicate that Merck's liability could be as high as $17.6 billion over the next decade or so, based on the possibility of 51,000 successful personal injury lawsuits with jury awards or settlements of $100,000 - $300,000 for patients claiming cardiac incidents, plus another $1-2 billion for nuisance lawsuits -- a total of almost $20 billion in corporate liability for personal injuries caused by Vioxx. By February 15, 2005, according to *The New York Times*, analysts estimated Merck's total liabilities stemming from the Vioxx debacle could run as high as $30 billion. These personal injuries and the resulting corporate liability could have been avoided if Merck had simply told the truth about Vioxx from the time it was introduced to the market.

161. Industry experts project that Merck's Vioxx-related liability exposure will be the largest a pharmaceutical company has ever faced in connection with a dangerous drug. Since

Wyeth, a competing pharmaceuticals company, was forced to remove its diet drugs, Pondimin and Redux from the market in 1997, that company has paid more than $13.6 billion in combined settlements and legal fees. The Wyeth recall affected only 6 million patients. Doctors wrote more than 100 million Vioxx prescriptions for at least 20 million patients during the Relevant Period. A study published in *The Lancet* in 2004 by FDA epidemiologist David Graham states that up to 140,000 Vioxx users in the U.S. suffered heart complications from the drug while Vioxx was on the market between 1999 and 2004.

162. In August 2005 Merck was found liable by a jury in Angleton, Texas, for the wrongful death of Robert Charles Ernst who had started taking Vioxx six months before he died. The jury also found Merck acted recklessly in selling Vioxx, despite having knowledge of the drug's heart risks.

D. THE NEW ENGLAND JOURNAL OF MEDICINE LEARNS THAT THE DATA MERCK SET FORTH AS THE RESULTS OF THE VIGOR STUDY WERE FALSE AND MISLEADING

163. On or about December 8, 2005, the editors of the *New England Journal of Medicine* published an editorial called an "Expression of Concern" relating to false data in Merck's report of a VIGOR study published in 2000.

164. In the editorial, the *New England Journal of Medicine* states that at least two Merck employees, one of which was likely to have been Defendant Reicin, knew about three additional myocardial infarctions at least two weeks before the authors submitted their 2000 article, "Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Rheumatoid Arthritis," N. Eng. J. Med. 2000; 343:1520-8, and for one-half month prior to publication of the article.

165. The editors of the New England Journal of Medicine continued:

> Lack of inclusion of the three [myocardial infarctions] resulted in an understatement of the difference in risk of myocardial infarction between the rofecoxib and naproxen groups (presented in the article as a reduction in the risk with naproxen but shown here as an increase in the risk with rofecoxib). It also resulted in the misleading conclusion that there was a difference in the risk of myocardial infarction between the aspirin indicated and aspirin not indicated groups.
>
> In addition, the memorandum of July 5, 2000, contained other data on cardiovascular adverse events that we believe would have been relevant to the article. ***We determined from a computer diskette that some of these data were deleted from the VIGOR manuscript two days before it was initially submitted to the Journal on May 18, 2000.***
>
> Taken together, these inaccuracies and deletions call into question the integrity of the data on adverse cardiovascular events in this article.

(Emphasis added).

166. In a later edition of the *New England Journal of Medicine*, the editors published Merck's response. Merck's explanation in no way changed the *New England Journal of Medicine*'s view, which responded to the Merck submission as follows:

> We wrote to the authors explaining the reasons for our concern and requested a written response. The authors' responses appear unedited elsewhere in this issue of the *Journal*.
>
> As part of our expression of concern, we also pointed out that three myocardial infarctions in the rofecoxib group were not included in the data submitted to the *Journal*. The authors state that these events did occur during the trial but did not qualify for inclusion in the article because they were reported after a "prespecified cutoff date" for the reporting of cardiovascular events. This date, which the sponsor selected shortly before the trial ended, was one month earlier than the cutoff date for the reporting of adverse gastrointestinal events. This untenable feature of trial design, which inevitably skewed the results, was not disclosed to the editors or the academic authors of the study.
>
> ***The information we have indicates that the VIGOR article, because it did not contain relevant safety data available to the authors more than four months before publication, did not***

> ***accurately reflect the potential for serious cardiovascular toxicity with rofecoxib. We therefore affirm our expression of concern.***

(Emphasis added).

VI. GOVERNMENTAL AND REGULATORY INVESTIGATIONS COMMENCE

167. Almost immediately after the Company made its September 30, 2004 Announcement, members of the medical community publicly called for a Congressional investigation into the facts and circumstances that enabled Merck to continue to market and distribute Vioxx while the Company possessed information indicating that the drug carried serious negative cardiovascular and thrombotic implications. Regulatory authorities commenced immediate investigations into Merck's conduct concerning the sale and marketing of Vioxx. The primary objective of the investigations was to determine the Defendants' knowledge of the dangers that Vioxx posed before and after the FDA approved the drug for prescription use in May 1999.

A. THE DEPARTMENT OF JUSTICE INVESTIGATION

168. On November 8, 2004, Merck filed with the SEC its Form 10-Q, for the Third Quarter 2004 (the "Third Quarter 2004 Form 10-Q"). In the Third Quarter 2004 Form 10-Q, Merck disclosed that the United States Department of Justice ("DOJ") had commenced a criminal investigation into the Vioxx debacle. According to Merck, the DOJ served a subpoena on the Company "requesting information related to the Company's research, marketing and selling activities with respect to Vioxx in a federal healthcare investigation under criminal statutes."

169. Although the Company did not disclose the scope of the DOJ's investigation, industry experts believe the DOJ will examine, among other things, whether the Defendants

misled regulators and/or manipulated federal health programs such as Medicare and Medicaid into paying for prescriptions of Vioxx even when its use was not warranted.

170. On May 12, 2005, the DOJ announced that it had launched a formal criminal investigation into the acts of Merck and its executives with respect to Vioxx.

B. THE SEC AND OTHER INVESTIGATIONS

171. In its Form 10-Q filed on November 8, 2004, Merck also disclosed that members of the SEC staff had advised the Company that the SEC was commencing an informal inquiry concerning Vioxx. Although the Company did not specifically address the scope or purpose of the SEC inquiry, the SEC is expected to examine whether Merck fully disclosed to the Company's investors information that Defendants possessed concerning Vioxx's risks and the corresponding threat to Vioxx's medical and commercial viability. It is also typical for the SEC to examine whether corporate insiders profited based upon their early knowledge of adverse news.

172. On or about January 28, 2005, the SEC raised the level of its probe into Merck's handling of the Vioxx debacle into a full-fledged investigation.

173. The Company has also received a number of Civil Investigative Demands ("CID") from a group of Attorneys General from ***thirty-one (31)*** states and the District of Columbia who are investigating whether the Company violated state consumer protection laws when marketing Vioxx. The Company also received a subpoena in September 2006 from the State of California Attorney General seeking documents and information related to the placement of Vioxx on California's Medi-Cal formulary.

C. CONGRESSIONAL INVESTIGATIONS AND THE NOVEMBER 18, 2004 SENATE FINANCE COMMITTEE HEARING

174. Soon after the Company's September 30, 2004 Announcement, Senate Finance Committee Chairman, Charles Grassley (R. Iowa), began to investigate the circumstances surrounding the Vioxx recall.

175. The opening testimony by Dr. Gurkirpal Singh, Adjunct Clinical Professor of Medicine at the Stanford University School of Medicine, explained how the early VIGOR study published in the *New England Journal of Medicine* in November of 2000 was misleading and improperly published because it failed to indicate that its findings were only preliminary and incomplete:

> Scientific publications in a medical journal are the most credible way to disseminate data about a medication. VIGOR data was published in the New England Journal of Medicine in November, 2000. A few weeks ago, Merck announced that the published VIGOR data was "preliminary" and that the "final" data was presented to the FDA. In my view, and all of my colleagues that I have consulted with, it is inappropriate to publish "preliminary" or incomplete data without clearly stating that the data are preliminary. This is especially true if the favorable data are complete but the unfavorable data are "preliminary" and likely to get worse. To the best of my knowledge, the VIGOR paper did not indicate anywhere that the data were preliminary or incomplete. Nor, did I ever see a correction or erratum indicating this fact subsequently – up until a few weeks ago, almost 4 years later.

176. Dr. Singh also characterized the VIGOR study as misleading in other critical aspects, constituting a deliberate suppression of the adverse effects of Vioxx from the public and the medical community in general:

> The VIGOR publication minimized the significance of heart attacks. While it prominently discussed the reduction of stomach bleeds in patients taking Vioxx, it did not mention that in spite of this, patients on Vioxx had more serious adverse events, and more hospitalizations than patients on Naproxen. The true rates for cardiovascular thrombotic adverse events (a prespecified study endpoint in the protocol), hypertension and congestive heart failure

> -- which were all higher in the Vioxx group -- were not shown in the paper at all.

177. On May 5, 2005, the House Government Reform Committee held a public hearing as part of its investigation, launched in November 2004, concerning the Vioxx withdrawal. The House Government Reform Committee's investigation shed further light on how Defendants trained Merck's sales representatives to engage in a campaign of deception that minimized the serious cardiovascular risks associated with Vioxx.

178. In response to the House Government Reform Committee's request that Merck produce a wide range of documents concerning Vioxx, Defendants produced over 20,000 pages of internal Company documents, including course curricula, bulletins to the field, training manuals, Company talking points, memoranda among senior executives, and promotional materials for use with physicians. On May 5, 2005, the minority members of the House Committee issued the "Congressional Memorandum," which summarized the "key documents" produced by Merck. Among other things, the Congressional Memorandum states:

> These documents provide an extraordinary window into how Merck trained its sales representatives and used them to communicate with physicians about Vioxx and its health risks. ***In fact, the documents may offer the most extensive account ever provided to Congress of a drug company's efforts to use its sales force to market to physicians and overcome health concerns.***

(Emphasis added).

179. The Congressional Memorandum discusses how Defendants trained Merck sales representatives, and provided them with false and misleading information, to "assuage any physicians concerns" that may have arisen as a result of "any public indication of Vioxx's safety risks."

180. The Congressional Memorandum also reveals that, pursuant to a Merck workbook entitled "Merck, Join the Club (March 2001)," sales representatives, when making a sales

presentation, were only permitted to use medical journal articles "***when those articles presented Merck products in a favorable light.***" (Emphasis added.) According to the Congressional Memorandum:

> One course workbook instructed participants that medical journal articles relating to Merck drugs fell into two categories: "approved" and "background." "Approved" articles were those to be discussed with doctors because they "provide solid evidence as to why [doctors] should prescribe Merck products for their appropriate patients." In contrast, "background" articles were not approved for use with physicians. According to the workbook, "These articles may contain valuable background information, but this information cannot be used, and the articles cannot be referenced, during sales discussions with your customers." ***In fact, discussing unapproved background articles with physicians "is a clear violation of Company Policy."*** Merck instructed representatives to refer any questions about these articles to the medical services department.

(Emphasis added).

181. The Congressional Memorandum reports how Defendants provided their sales representatives with materially false and misleading information concerning the results of the VIGOR Study and the safety of Vioxx:

> Soon after the release of these results, physicians began asking Merck representatives whether Vioxx could cause heart attacks. ***On April 28, 2000, in a bulletin to "all field personnel with responsibility for Vioxx," Merck provided a "new resource" "to ensure that you are well prepared to respond to questions about the cardiovascular effects of Vioxx." The resource was the "Cardiovascular Card."***
>
> The Cardiovascular Card was a tri-fold pamphlet containing data that supported the safety of Vioxx. One panel featuring the headline "Overall Mortality Rates," indicated that patients on Vioxx were 11 times less likely to die than patients on standard anti-inflammatory drugs, and 8 times less likely to die from heart attacks and strokes. [] Another panel indicated that the rate of heart attack among patients on Vioxx was less than half of the rate of patients receiving placebo and virtually identical to that of patients receiving other anti-inflammatory drugs.

> ***Merck gave its representatives specific instructions on how to use the Cardiovascular Card. According to these instructions, Merck's representatives were to refer to the mortality data and "use this page to show physicians that in terms of mortality, which is most important to the physician and their patients, the rate for total mortality and cardiovascular mortality was low." The data presented in the Cardiovascular Card appears to have little or no scientific validity. The card did not present actual numbers of events or any statistical tests of significance, which are standard in medical communications. It also did not contain any information from the VIGOR study, the most recent study of cardiovascular safety in rheumatoid arthritis patients.***
>
> Instead, the card presented pooled data from clinical trials conducted prior to the drug's approval in osteoarthritis patients. ***For several reasons, however, these studies were not appropriate for an overall analysis of cardiovascular safety.***

(Emphasis added).

182. The Congressional Memorandum sets forth a number of reasons why Merck's use of the Cardiovascular Card was improper:

- Vioxx's pre-approval studies involved few patients taking the doses of Vioxx that were linked to heart problems. According to the FDA, fewer than 300 patients in these studies took as much as 50 mg per day of Vioxx for more than 6 months, compared to approximately 4,000 patients in the VIGOR study. As a result, the studies were not nearly as sensitive as VIGOR in detecting a possible problem with the drug.

- The pre-approval studies had been conducted to test the efficacy of the drug to treat pain, not to assess whether the drug caused heart attacks and strokes. None of these early studies had included an expert assessment of whether adverse events were related to the cardiovascular system. Such an "adjudication" process improves the quality of the data and was part of the VIGOR study.

- The pre-approval studies varied widely, involving different doses, different patient populations, and different comparator drugs. In 1999, prior to Vioxx's approval, FDA had expressed serious concerns about combining these disparate studies in a single safety analysis.

- The analyses presented in the Cardiovascular Card were not drawn from a scientific paper. The card's two references included "data on file" at Merck and a brief research abstract from a 1999 meeting of the American College of Rheumatology.

- When given the opportunity, FDA scientists have expressed "serious concerns" about using the data summarized on the Cardiovascular Card to address cardiovascular safety. One FDA medical reviewer, in a briefing with Committee staff, said that the relevance of Vioxx's pre-approval studies to the drug's cardiovascular safety was "nonexistent" and that it would be "ridiculous" and "scientifically inappropriate" to present mortality comparisons from these trials to physicians.

183. The Congressional Memorandum also reports that, notwithstanding their awareness of the safety risks, Defendants provided financial incentives to Merck sales representatives to promote Vioxx:

> In the spring of 2000, Merck launched the "2000 Field Incentive Plan for Vioxx." This plan promised reward to the company's hospital representatives, specialty representatives, and other sales representatives if the Vioxx share of the market exceeded certain thresholds. As a bulletin to field staff explained:
>
> 1. Hit 51% . . . for at least one month by March 2000 and get $2,000!
>
> 2. Hit 55% . . . for at least one month between April and December 2000 and get $2,000!
>
> 3. Hit 61% . . . for at least one month between April and December 2000 and get $2,000!

D. ADDITIONAL INFORMATION COMES OUT ON THE DANGER OF VIOXX AND HOW IT WAS IMPROPERLY SOLD TO CONSUMERS THROUGH A MASSIVE MARKETING CAMPAIGN

184. On December 6, 2004, *The New York Times*, in an article entitled "With or Without Vioxx, Drug Ads Proliferate," reported on the likely impact of the inordinate amount of money that Merck spent on advertising Vioxx to the market:

> Critics complain that huge sums Merck spent to advertise Vioxx directly to consumers stimulated demand for the drug at the expense of cheaper -- and perhaps safer -- over-the-counter alternatives like ibuprofen.

In fact, in 2004, notwithstanding Defendants' knowledge concerning Vioxx's adverse cardiovascular profile, which jeopardized the drug's commercial viability and its ability to generate substantial revenues over the life of Merck's patent, Merck spent more than $78 million on direct-to-consumer advertisement spending until they withdrew Vioxx in September of that year.

185. On December 7, 2004, *The Wall Street Journal*, in an article entitled "Celebrex Less Risky Than Vioxx," reported that results from a University of Pennsylvania study indicated that "painkillers known as Cox-2 inhibitors don't all carry the same risk for heart attacks." *The Wall Street Journal* article also reported that the study, which was published in the December 6, 2004 online edition of Annals of Internal Medicine, found that:

> In the final analysis, the odds of a Vioxx user having a heart attack were 2.72 times higher than a Celebrex user, after adjustment for several factors, including body mass. That finding [] was statistically significant.

186. On December 8, 2004, Defendants issued a press release announcing Merck's financial results for the fourth quarter 2004, the period ending September 30, 2004. Among other things, the Form 10-Q commented on the impact of the Vioxx withdrawal on Company's performance:

> Merck anticipates fourth-quarter 2004 EPS [earnings per share] of $0.48 to $0.53, which includes the impact of approximately $700 to $750 million in foregone sales of Vioxx and potential additional fourth-quarter costs for the withdrawal of Vioxx. As a result, Merck anticipates full-year 2004 EPS guidance of $2.59 to $2.64, which includes the expectation that the impact of the withdrawal will negatively affect full-year EPS by $0.50 to $0.55.

187. That same day, *The New York Times*, in an article entitled "Merck's Board Appoints Panel to Investigate Handling of Vioxx," reported that the Company had commenced "an independent investigation into whether the company acted properly regarding Vioxx." The article also reported that "[t]he board [of directors] has appointed a seven-member special committee of outside directors to investigate Merck's actions and to respond to shareholder litigation." The article further reported that a "spokeswoman for Merck said she did not know whether the directors had opened the investigation at the request of federal prosecutors, who are also investigating Merck."

188. On December 19, 2004, *The New York Times*, in an article entitled "Medicine Fueled by Marketing Intensified Trouble for Pain Pills," reported on Defendants' motivation to conceal the cardiovascular risks attributed to Vioxx, i.e., to increase sales:

> ***But having spent hundreds of millions of dollars to develop [Vioxx,] the maker[] of . . . Vioxx, cheered on by Wall Street, had every motivation to expand their market[] beyond the older people most at risk of ulcers to encourage [Vioxx's] use by millions more people of all ages.***

(Emphasis added).

189. On December 21, 2004, *The Wall Street Journal*, in an article entitled "Management Missteps in '04 Hurt Companies, Endangered Customers," emphasized how Defendants "put customers at risk" by repudiating any reports that raised questions about the safety profile of Merck's "blockbuster drug" Vioxx:

> ***Merck's top executives put customers at risk for years – and badly damaged the company's reputation – by countering concerns raised by outside scientists about the potentially serious side effects of Vioxx, its big-selling painkiller. When CEO Raymond Gilmartin announced in September that Merck was pulling Vioxx off the market because of a study that tied the drug to heart-attack and stroke risks, he said that the findings were "unexpected" and that Merck was responding swiftly to the results.***

> ***But internal Merck e-mails suggest that the company fought for more than four years to quash safety concerns raised by academics and other researchers about the cardiovascular risks of Vioxx.***

(Emphasis added).

190. On January 20, 2005, the *CBS Market Watch*, in an article entitled "Study: Merck's Vioxx Was Overprescribed, Misused," reported that researchers at the University of Pennsylvania, who were authors of a study that would be published in the *Archives of Internal Medicine* January 2005 edition, stated that "Vioxx was prescribed mainly to patients who stood to gain little benefit from the medication but were still exposed to its risks of heart problems." In addition, the article reported:

> The research – gleaned from national databases – revealed that prescriptions of Merck's withdrawn arthritis therapy and other so-called COX-2 inhibitor drugs rose the fastest among patients with low or no risk of stomach bleeding, the complication that Vioxx and other Cox-2s were designed to prevent.

191. The article reported that the researchers "blamed the phenomenon largely on drug companies' aggressive marketing campaigns and a new trend by doctors and their patients to view drugs designed for a specific purpose as 'one size fits all' miracle pills."

E. IT IS REVEALED THAT MERCK HAD A LONG-STANDING PRACTICE OF HIDING INFORMATION REGARDING ADVERSE DRUG TRIALS

192. On May 31, 2005, *The New York Times*, in an article entitled "Despite Vow, Drug Makers Still Withhold Data," reported:

> Within the drug industry, companies are sharply divided about how much information to reveal, both about new studies and completed studies for drugs already being sold. The split is unusual in the industry, where companies generally take similar stands on regulatory issues.
>
> Eli Lilly and some other companies have posted hundreds of trial results on the Web, and pledged to disclose all results for all drugs they sell. ***But other drug makers, including Merck . . . , release***

> ***less information and are reluctant to add more, citing competitive pressures***.
>
> ***[T]he companies can hide negative trial results by refusing to publish studies, or by cherry-picking and highlighting the most favorable data from studies they publish***.
>
> * * *
>
> Lilly has also posted the results of many completed studies to clinicalstudyresults.org, the website created last September by PhRMA. That site now contains some information on nearly 80 drugs that are already on the market. ***Both Lilly and Glaxo have posted detailed summaries of hundreds of studies . . . . Merck has posted none***.

(Emphasis added).

193. The next day, June 1, 2005, *The New York Times*, in an article entitled "Hiding the Data on Drug Trials," reported further details concerning certain pharmaceutical companies' efforts to hide negative trial results from the public:

> By law, the companies are supposed to register important trials with a government Web site. Most manufacturers are complying, but the three big obfuscators -- [including] Merck [] -- are often getting around the requirement by not naming the drugs they are testing, instead using phrases like "an investigational drug." ***Merck was the worst offender, failing to provide a drug's name some 90 percent of the time***.

(Emphasis added).

194. Notwithstanding Defendants' failure to disclose Vioxx's significant cardiovascular and thrombotic risk to the market, it is clear that Defendants were well aware from 1999 through prior to September 30, 2004, of the significant number of heart attacks and cardiovascular events that were attributed to Vioxx. The FDA's Adverse Event Reporting System ("AERS") database is a computerized system for collecting and maintaining information about adverse events reported by drug manufacturers, health professionals, and others.

195. According to the AERS, during the Relevant Period, almost 15,400 adverse cardiac-related events experienced by persons taking Vioxx, including myocardial infarctions, cardiac arrests, and cardiac failures, which resulted in such serious outcomes as hospitalization, life threatening conditions, and even death, were reported to the FDA, as indicated below:

1999	2000	2001	2002	2003	2004	**Total**
331	2,248	2,899	2,915	2,435	4,452	**15,370**

196. It is widely understood that adverse events can be dramatically underreported. According to Brian Stom, author of a leading treatise on pharmacoepidemiology:

> It has been estimated that rarely more than 10% of serious ADRs [adverse drug reactions], and 2-4% of non-serious reactions are reported to the British spontaneous reporting program. A similar estimate is that the FDA receives by direct report less than 1% of serious ADRs.

Thus, Defendants well understood that the actual number of adverse events associated with Vioxx was significantly higher than the reported number.

197. According to estimates in a study led by Dr. David Graham, an FDA safety official, which were made public after Merck withdrew Vioxx from the market on September 30, 2004, use of Vioxx may have led to more than 139,000 heart attacks and cardiovascular events, 30% to 40% of which resulted in death.

VII. FIVE DIFFERENT JURIES FIND MERCK LIABLE FOR CARDIOVASCULAR INJURY OR DEATH CAUSED BY VIOXX

198. As previously discussed, individual and putative class actions have been filed against the Company in state and federal courts alleging personal injury and/or economic loss with respect to the purchase or use of Vioxx. All such actions filed in federal court are coordinated in a multidistrict litigation in the U.S. District Court for the Eastern District of Louisiana (the "MDL") before District Judge Eldon E. Fallon. A number of such actions filed in

state court are coordinated in separate coordinated proceedings in state courts in New Jersey, California and Texas, and the counties of Philadelphia, Pennsylvania, and Washoe and Clark Counties, Nevada.

199. As of June 30, 2007, the Company had been served or named as a Defendant in approximately 26,950 lawsuits, which include approximately 45,225 plaintiff groups, alleging personal injuries resulting from the use of Vioxx, and in approximately 266 putative class actions alleging personal injuries and/or economic loss (collectively, "Vioxx Product Liability Lawsuits"). Of these lawsuits, approximately 8,575 lawsuits representing approximately 23,450 plaintiff groups are slated to be in the federal MDL and approximately 16,400 lawsuits representing approximately 16,400 plaintiff groups are included in a coordinated proceeding in New Jersey Superior Court before Judge Carol E. Higbee.

200. In addition, Merck has entered into a tolling agreement (the "Tolling Agreement") with the MDL Plaintiffs' Steering Committee that establishes a procedure to halt the running of the statute of limitations as to certain categories of claims arising from the use of Vioxx by non-New Jersey citizens. The Tolling Agreement applies to individuals who have not yet filed lawsuits, but who eventually do file lawsuits and who seek to toll claims alleging injuries resulting from a thrombotic cardiovascular event that results in a myocardial infarction or ischemic stroke.

201. Juries have now found in favor of plaintiffs and against Merck ***five*** times, finding each time that Merck was liable for cardiovascular injury or death caused by Vioxx.

A. MERCK IS FOUND LIABLE FOR THE WRONGFUL DEATH OF ROBERT ERNST DUE TO VIOXX AT A TRIAL IN ANGLETON, TEXAS

202. In July 2005, Carol Ernst, the widow of Robert Charles Ernst, a 50-year old tri-athlete who completed a marathon three months before he died suddenly in his sleep in May

2001, brought Merck to trial in Angleton, Texas, to face allegations of the wrongful death of her husband. Mr. Ernst had started taking Vioxx for tendonitis about six months before he died.

203. After deliberating for a day and a half, the jury decided the following issues in the affirmative:

- Did Merck fail to warn doctors about Vioxx's dangers, and did that failure cause the death of Robert Ernst?
- Could Vioxx have been designed in a way that made it less risky?
- Did Merck cause Robert Ernst to die?

204. The jury gave Robert C. Ernst's widow, Carol, $24.5 million for mental anguish and economic losses. Jurors also said she should be awarded an additional $229 million in punitive damages after finding that Merck acted recklessly in selling Vioxx, despite having knowledge of the drug's heart risks.

205. Merck's shares fell $2.35, or 7.7 percent, to close at $28.06 after the verdict was announced. The drop erased about $5 billion from Merck's market capitalization.

B. MERCK IS FOUND LIABLE IN BARNETT V. MERCK

206. In August 2006, in Barnett v. Merck, a jury in New Orleans, Louisiana, returned a plaintiff verdict in the second federal Vioxx case to go to trial. The jury awarded the plaintiff, a former FBI agent, $50 million in compensatory damages and $1 million in punitive damages. On June 5, 2007, Judge Fallon denied Merck's motion for judgment as a matter of law and denied in part Merck's motion for a new trial on all issues. The Court allowed the plaintiff to choose whether to accept a reduced damages award of $1.6 million ($600,000 in compensatory damages and $1 million in punitive damages) or to have a re-trial. On June 20, 2007, the plaintiff accepted the Court's reduced damage award of $1.6 million, upholding the award of $1 million in punitive damages, and on June 28, 2007, Judge Fallon entered judgment in that amount.

C. MERCK FOUND LIABLE FOR THE DEATH OF LEO GARZA

207. In April 2006, in Garza v. Merck, a jury in Rio Grande City, Texas, returned a verdict in favor of the plaintiffs. On December 21, 2006, the Court entered judgment for plaintiffs in the amount of $7.75 million, plus interest. Leo Garza had died in 2001 at age 71 after taking Vioxx for only 17 days.

D. A NEW JERSEY COURT FINDS FOR PLAINTIFFS IN HUMESTON V. MERCK AWARDING $48.5 MILLION FOR HUMESTON'S VIOXX-INDUCED HEART ATTACK

208. On March 12, 2007, in New Jersey Superior Court before Judge Higbee, the jury found for plaintiffs in the Humeston case, awarding compensatory damages to Mr. Humeston in the amount of $18 million and to Mrs. Humeston in the amount of $2 million. The jury also awarded $27.5 million in punitive damages. Humeston, a postal worker from Boise, Idaho, suffered a heart attack on September 18, 2001 at age 56 after taking Vioxx.

E. A NEW JERSEY COURT FINDS FOR PLAINTIFFS IN MCDARBY V. MERCK

209. In April 2006, at a trial in Superior Court of New Jersey, Law Division, Atlantic County involving John McDarby, the jury determined that Vioxx substantially contributed to the heart attack of Mr. McDarby. Defendant Anstice testified at the trial. Merck set forth its "Naproxen Hypothesis," which was rejected by the jury. The jury also concluded that, in each case, Merck violated New Jersey's consumer fraud statute, which allows plaintiffs to receive their expenses for purchasing the drug, trebled, as well as reasonable attorneys' fees. The jury awarded $19.7 million: (1) $4.5 million in compensatory damages to Mr. McDarby and his wife, who also was a plaintiff in that case, and (2) punitive damages of $9 million. On June 8, 2007, Judge Higbee denied Merck's motion for a new trial. On June 15, 2007, Judge Higbee awarded approximately $4 million in the aggregate in attorneys' fees and costs.

VIII. DEFENDANTS' IMPROPER FAILURE TO DISCLOSE CONTINGENT LIABILITIES AND SIGNIFICANT RISKS AND UNCERTAINTIES

210. In addition to their failure to disclose known problems with Vioxx, Defendants also attempted to deceive investors during the Relevant Period by failing, in Merck's financial statements, to disclose its contingent liabilities and significant risks and uncertainties related to Vioxx, in conformity with Generally Accepted Accounting Principles ("GAAP").

211. GAAP are recognized by the accounting profession and the SEC as the uniform rules, conventions, and procedures necessary to define accepted accounting practice at a particular time. GAAP requires that financial statements disclose contingencies when it is at least reasonably possible (i.e., a greater than slight chance) that a loss may have been incurred. SFAS No. 5, ¶ 10. The disclosure shall indicate the nature of the contingency and shall give an estimate of the possible loss, a range of loss, or state that such an estimate cannot be made. *Id.*

212. The SEC considers the disclosure of loss contingencies to be so important to an informed investment decision that it issued Article 10-01 of Regulation S-X [17 C.F.R. § 210.10-01], which provides that disclosures in interim period financial statements may be abbreviated and need not duplicate the disclosure contained in the most recent audited financial statements, except that "where material contingencies exist, disclosure of such matters shall be provided even though a significant change since year end may not have occurred."

213. In addition, GAAP requires that financial statements disclose significant risks and uncertainties associated with an entity's business. *See* Disclosure of Risks and Uncertainties, Statement of Position No. 94-6.

214. In violation of GAAP, Merck's Relevant Period financial statements improperly failed to disclose that the Company's sales of Vioxx exposed it to substantial risks and uncertainties, as detailed herein.

215. Defendants also failed to disclose, in the Company's SEC filings, that the Company lacked adequate insurance to cover the known contingencies relating to Vioxx, including the personal injury litigation. According to Merck's October 21, 2004 press release, Merck has only about $630 million maximum coverage for the Vioxx personal injury lawsuits. Analysts have estimated the Company's Vioxx-related liability to be as high as $30 billion. Merck has admitted that "the Company's insurance coverage with respect to the Vioxx lawsuits will ***not*** be adequate to cover its defense costs and any losses." (Emphasis added.)

216. Instead of disclosing the very real and substantial contingencies caused by Vioxx personal injury claims and other Vioxx litigation, in the Company's SEC filings, including the 2003 Form 10-K and the first quarter 2004 Form 10-Q, Defendants attempted to minimize the financial risk by referring generally to product liability and other suits and representing:

> There are various other legal proceedings, principally product liability and intellectual property suits involving the Company, which are pending. While it is not feasible to predict the outcome of these proceedings or the proceedings discussed above, in the opinion of the Company, all such proceedings are either adequately covered by insurance or, if not so covered, should not ultimately result in any liability that would have a material adverse effect on the financial position liquidity or results of operations of the Company.

217. The Company has admitted that unfavorable outcomes in Vioxx litigation could have a material adverse effect on the Company's financial position, liquidity and results of operations.

218. As of December 31, 2006, the Company had a reserve of $858 million solely for its future legal defense costs related to Vioxx litigation.

> During the first six months of 2007, the Company spent approximately $258 million in the aggregate in legal defense costs worldwide, including $137 million in the second quarter, related to (i) the Vioxx Product Liability Lawsuits, (ii) the Vioxx Shareholder Lawsuits, (iii) the Vioxx Foreign Lawsuits, and (iv)

> the Vioxx Investigations (collectively, the "Vioxx Litigation"). In the second quarter of 2007, the Company recorded a charge of $210 million, to increase the reserve solely for its future legal defense costs related to the Vioxx Litigation to $810 million at June 30, 2007.

IX. RELEVANT PERIOD EVENTS AND DEFENDANTS' FALSE AND MISLEADING STATEMENTS AND/OR OMISSIONS

A. MAY 1999-DECEMBER 1999 EVENTS AND FALSE AND MISLEADING STATEMENTS AND/OR OMISSIONS

219. During the time period from May 21, 1999, when Vioxx was first introduced on the market, through December 1999, the Defendants made and/or caused to be issued numerous materially false and misleading statements and/or omissions of material facts.

(i) Merck Announces FDA Approval Of Vioxx

220. On May 21, 1999, Merck issued a press release in which it announced the FDA had approved Vioxx for the relief of osteoarthritis, menstrual pain and other forms of acute pain. Merck stated the most common side effects reported in clinical trials with Vioxx were upper-respiratory infection, diarrhea and nausea. The press release stated Vioxx should be available in pharmacies by mid-June 1999. The press release failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx. Defendants were aware of these risks from internal studies, including Study 090, the results of which Defendants failed to disclose to the FDA or to the public.

221. In an internal email, Defendant Scolnick derided the FDA. Merck had exerted pressure on the FDA in 1999 to approve Vioxx without a heart-attack warning label. Scolnick wrote that winning the Vioxx label it did (which had no heart-attack warning) was a "miracle."

222. On July 23, 1999, the Company issued a press release (the "July 23, 1999 Press Release") in which it announced its results for the second quarter of 1999. In the July 23, 1999

Press Release, the Company made the following materially false and misleading statements and/or omissions: "Sales growth for the quarter and the first half of 1999 was led by the established major products, including the 1999 launch of Vioxx …." The press release failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

223. On August 11, 1999, the Company filed its Form 10-Q for the Second Quarter 1999 (the "Second Quarter 1999 Form 10-Q") with the SEC. The Form 10-Q contained, among others, the following materially false and misleading statement and/or omission of material facts:

> Since [the FDA approval of Vioxx], more than 400,000 U.S. patients have taken the product. Merck has introduced "Vioxx" in nine other countries including the United Kingdom, Switzerland and Mexico. The Company is conducting additional clinical studies with 'Vioxx' to determine whether it is useful in treating rheumatoid arthritis and in preventing and treating Alzheimer's disease. Studies will begin later this year to ascertain whether "Vioxx" might help prevent colon cancer.

The Second Quarter 1999 Form 10-Q failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the

fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

(ii) Merck Promotes Vioxx While Purposely Failing To Disclose The Cardiovascular Risks Of The Drug

224. On October 19, 1999, the Company issued a press release entitled "Publication Shows New Medicine Vioxx Relieved Menstrual Pain" (the "October 19, 1999 Press Release"). The October 19, 1999 Press Release stated in pertinent part: "Since its approval by the FDA in May, more than 2.2 million prescriptions have been written for Vioxx in the United States, making it one of the most successful product introductions in the pharmaceutical industry's history." The October 19, 1999 Press Release failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

225. On October 21, 1999, Merck issued a press release (the "October 21, 1999 Press Release") entitled "Merck's Earnings Per Share Increase 14% for the Third Quarter 1999." The October 21, 1999 Press Release made the following materially false and misleading statements and/or omission of material facts regarding Merck's performance:

> In just 20 weeks on the market in the United States, Vioxx has become the country's fastest growing prescription arthritis medicine. U.S. physicians have written more than 2 million prescriptions for Merck's newest medicine, which is used to relieve the signs and symptoms of osteoarthritis, manage acute pain in adults and treat menstrual pain. In September, Merck entered an agreement with Collagenex, a leader in dental products, to co-promote Vioxx to dentists, periodontists and oral surgeons in the U.S. Dentists in the U.S. write more than 1.8 million prescriptions monthly for the relief of pain.
>
> Merck has introduced Vioxx in 22 other countries, including the United Kingdom, Switzerland and Mexico. The Company is conducting extensive clinical studies with Vioxx to evaluate its efficacy in the treatment of rheumatoid arthritis and in the prevention and treatment of Alzheimer's disease. Studies will begin later this year to ascertain whether Vioxx might help prevent colon cancer. In a recent interference decision, the U.S. Patent and Trademark Office held that Merck is entitled to exclusive patent rights covering Vioxx and structurally-related compounds.

The October 21, 1999 Press Release failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck,

internal e-mails, and non-public communications to Merck from physicians and medical scientists.

226. On October 25, 1999, the Company issued a press release (the "October 25, 1999 Press Release") in which the Company stated that Vioxx produced fewer ulcers in osteoarthritis patients than patients taking ibuprofen. Merck announced the results of a new study showing that osteoarthritis patients taking Vioxx developed fewer stomach ulcers than patients taking ibuprofen. The October 25, 1999 Press Release failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

227. On or about November 12, 1999, Merck filed its Form 10-Q for the third quarter 1999 (the "Third Quarter 1999 Form 10-Q") with the SEC. In the Third Quarter 1999 Form 10-Q, the Company made the following materially false and misleading statements and/or omissions of material fact:

> In just 20 weeks on the market in the United States, 'Vioxx' has become the country's fastest growing prescription arthritis medicine. U.S. physicians have written more than 2 million prescriptions for Merck's newest medicine, which is used to relieve the signs and symptoms of osteoarthritis, manage acute pain in adults and treat menstrual pain. In September, Merck entered an agreement with CollaGenex, a leader in dental products, to co-promote 'Vioxx' to dentists, periodontists and oral surgeons

> in the U.S. Dentists in the U.S. write more than 1.8 million prescriptions monthly for the relief of pain.
>
> Merck has introduced 'Vioxx' in 22 other countries, including the United Kingdom, Switzerland and Mexico. The Company is conducting extensive clinical studies with 'Vioxx' to evaluate its efficacy in the treatment of rheumatoid arthritis and in the prevention and treatment of Alzheimer's disease. Studies will begin later this year to ascertain whether 'Vioxx' might help prevent colon cancer. In a recent interference decision, the U.S. Patent and Trademark Office held that Merck is entitled to exclusive patent rights over 'Vioxx' and structurally-related compounds.

The Third Quarter 1999 Form 10-Q failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

228. On November 23, 1999, the Company issued a press release (the "November 23, 1999 Press Release") entitled "In a Study Published in the *Journal of the American Medical Association* ("JAMA"), Vioxx Significantly Reduced Risk of Serious Gastrointestinal Side Effects Compared to Other NSAIDS." The November 23, 1999 Press Release contained the following materially false and misleading statements and/or omissions of material fact:

> Vioxx, the new medicine for osteoarthritis from Merck & Co., Inc., significantly reduced the risk of gastrointestinal (GI) side effects such as symptomatic ulcers and bleeding compared to three commonly prescribed non-steroidal anti-inflammatory drugs (NSAIDs), according to a new study being published in tomorrow's issue of the *Journal of the American Medical Association.*
>
> * * *
>
> Common side effects reported in clinical trials with Vioxx were upper-respiratory infection, diarrhea, nausea and high blood pressure. People who have had an allergic reaction to Vioxx, aspirin or other NSAIDs should not take Vioxx. Safety and effectiveness in children below the age of 18 has not been studied.

The November 23, 1999 Press Release failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

229. On December 9, 1999, the Company issued a press release ("December 9, 1999 Press Release") entitled "Innovative Medicines Drive Revenue and Earnings Growth, Merck Tells Analysts." In the December 9, 1999 Press Release, the Company made the following materially false and misleading statements and/or omissions:

> Mr. Gilmartin reaffirmed that Merck's growth strategy, which is based on breakthrough research, has produced 15 innovative medicines since 1995, "all of which are meeting or beating the Company's expectations." He noted that Merck's internal research capability, complemented by external collaborations, excellent

capabilities in manufacturing and marketing, and Merck-Medco's proven health management solutions will help maintain the Company's record of success.

Given our progress on all these fronts, … "we are confident in our ability to deliver earnings growth rates competitive with the other leading health care companies through the year 2002, notwithstanding the expiration of several patents during this period," Mr. Gilmartin said.

* * *

Five Key Medicines Pave The Way For Growth

Vioxx, Merck's newest product, along with Zocor, Fosamax, Singulair and Cozaar/Hyzaar are well-positioned to be important drivers of future growth, Mr. Gilmartin said.

After only 28 weeks on the U.S. market, Vioxx, the once-a-day, anti-inflammatory COX-2 specific inhibitor (a coxib*) to treat the signs and symptoms of osteoarthritis and relieve acute pain, is Merck's "biggest, fastest and best prescription drug launch ever, Mr. Anstice said. Vioxx is gaining ground as the coxib of choice, achieving more than 40% of new U.S. prescriptions in its class. To date, Merck has launched Vioxx in more than 30 countries and it was the first coxib to receive mutual recognition approval for marketing in all the European Union countries. The initial uptake of Vioxx in the United Kingdom, Sweden and Germany -- the only E.U. countries where the product has been launched -- has been excellent. Within 14 weeks on the market in Switzerland, Vioxx achieved more than a 50% share of the coxib class. Merck is also evaluating Vioxx for the treatment of rheumatoid arthritis and the prevention and treatment of Alzheimer's disease, and will be studying the medicine's ability to help prevent colon cancer.

Proven Ability to Demonstrate the Value of Our Medicines

"The landmark clinical trials we conduct," Mr. Gilmartin said, "show how our innovative medicines save lives, reduce the burden of disease, and help replace more expensive medical treatments. The acceptance of our new drugs on managed care formularies and the rate at which they are approved for reimbursement in heavily regulated markets such as Europe – at prices that reflect their value – are solid proof that we can demonstrate the value of our medicines to patients, health care providers, managed care organizations and governments."

* * *

Investing in Our Growth Strategy

"Merck's growth strategy in breakthrough research, internal growth, and managed pharmaceutical care continues to pay off," Mr. Gilmartin said. "Given our results to date and our excellent potential for the future, we believe that the best way to continue to create value for our shareholders is to invest in internal growth, rather than expand through mergers and major acquisitions."

* * *

Merck's Growth Strategy is Working

New and recently introduced drugs are accounting for an increasingly large percentage of the Company's total revenues, while the Merck medicines that will lose patent protection (in 2000-2001) continue to decline in significance.

Mr. Gilmartin said that the Company is comfortable with the range of earnings per share (EPS) estimates for the full year 2000 of $2.71 to $2.81 and that it would be reasonable to expect earnings to be at the upper portion of this range. Analysts estimate that Merck's 2000 EPS will be $2.65 to $2.81. He also reiterated Merck's 1999 EPS guidance of $2.43 to $2.46.

The December 9, 1999 Press Release and the December 16, 1999 Form 8-K filed by Merck with the SEC (attaching a copy of the December 9, 1999 Press Release as an exhibit), both failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies

conducted by or known of by Merck, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

(iii) Analysts Embrace The Defendants' False And Misleading Statements

230. During the time period from January 1, 1999 through December 31, 1999, analysts followed Defendants' public statements and announcements closely in connection with reporting Company developments to investors. Analysts routinely repeated Defendants' materially false and misleading statements which failed to disclose material facts, using such statements as the basis for their reports. For example:

- On October 21, 1999, CIBC World Markets issued a report on Merck. It rated Merck a "Buy," with a target price of $77. It further provided: Vioxx followed up 2Qs99's strong debut of $97 million with an additional $111 million this quarter. We have high hopes for Vioxx to continue early trends and remain optimistic that sales will approach $350 million this year;

- On December 10, 1999, Dain Rauscher Wessels issued a report on Merck. It rated Merck a "Buy," with a price target of $89. It further provided: Vioxx…continues to perform well and is narrowing the gap between itself and…Celebrex. After 28 weeks on the market Vioxx is capturing 150,000 new prescriptions per week domestically, up more than 50% from three months prior…. Vioxx is also being rapidly adopted by managed care providers as the coxib of choice; and

- On December 16, 1999, Paine Webber issued a report on Merck. It rated Merck "Attractive," with a price target of $71.50 and noted that the most recent weekly prescriptions annualized at a run rate in excess of $1.0 billion. It further provided: "We recently raised our U.S. revenue assumptions for 1999 to $370 million. For 2000 we raised our worldwide Vioxx forecast to $1.5 billion."

231. Each of the Defendants statements made from May 21, 1999 through December 31, 1999 concerning Vioxx and/or Merck's fiscal 1999 sales performances was materially false and misleading when issued because each statement failed to disclose information known to the

Company -- that Vioxx was associated with negative cardiovascular and thrombotic events such that Vioxx's medical and commercial viability was threatened even before Merck received FDA approval to sell the drug at the beginning of the Relevant Period. The true but concealed and/or misrepresented facts included, but were not limited to:

- Merck's unpublished Study 090 concluded that Vioxx users were six times more likely to have severe cardiovascular events than users of other NSAIDS;
- Internal Merck e-mails authored from 1996 through May 1997 reveal that even before the FDA approved Vioxx for prescription use, Merck knew of the significant Vioxx-related cardiovascular and thrombotic risks;
- Substantial data existed in 1999 that Vioxx was associated with a higher risk of cardiovascular events than other NSAIDs;
- On December 16, 1999, Merck had received the December 16, 1999 FDA Letter admonishing Defendants for misleading the public by using deceptive promotional materials that suggested Vioxx had a superior safety profile to other NSAIDS, which was not demonstrated by substantial evidence; and
- The Company could not maintain the positive Vioxx sales results that it was experiencing because of the known risks to Vioxx's medical and commercial viability.

B. 2000 EVENTS AND FALSE AND MISLEADING STATEMENTS AND/OR OMISSIONS

232. In 2000, the Defendants made and/or caused to be issued numerous materially false and misleading statements and/or omissions of material facts concerning Vioxx and the drug's medical and commercial viability.

(i) Merck Previews Year-End 1999 Results

233. On January 27, 2000, the Company issued a press release (the "January 27, 2000 Press Release"), entitled "Merck's Qtr Net Up 14% As Old, New Remedies Shine," announcing Merck's fourth quarter and year-end financial results. In the January 27, 2000 Press Release, the

Company made the following materially false and misleading statements and/or omissions of material fact:

> Merck & Co. Inc., the No. 1 U.S. drug company, said on Wednesday its fourth quarter profits rose 14 percent, in line with Wall Street forecasts, on strong sales of established and newer medicines, including the pain fighter Vioxx.
>
> * * *
>
> Drug sales were helped by Vioxx, an osteoarthritis and acute pain medicine launched in May. The number of U.S. prescriptions for the drug topped 5 million in the quarter, making it the nation's fastest growing prescription arthritis medicine, Merck said.

The January 27, 2000 Press Release failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. This January 26, 2000 Press Release and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, internal e-mails, and non-public communications to Merck from physicians medical scientists.

234. On or about March 1, 2000, Merck issued its Annual Report to investors (the "1999 Annual Report"). The Company's 1999 Annual Report made, among others, the following materially false and misleading representations and/or omissions of material fact concerning Vioxx:

> Merck researchers knew they had a winner in Vioxx. The results proved them right. Since its launch last year, Vioxx has brought immense relief to people suffering from osteoarthritis and, in countries where it is prescribed for this use, acute pain. Now, these same researchers hope their studies of the effect of this breakthrough medicine on rheumatoid arthritis, colon cancer and Alzheimer's disease will bring even more victories to patients worldwide.

The 1999 Annual Report failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. This 1999 Annual Report, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, internal e-mails, and non-public communications to Merck from physicians medical scientists.

235. On March 22, 2000, Merck filed with the SEC the Company's Form 10-K, signed by Defendants Gilmartin, and Lewent (the "1999 Form 10-K"). In the 1999 Form 10-K, Defendants made the following materially false and misleading statements and/or omissions of material fact:

> In 1999, sales of Merck human health products grew 15%, including a three point increase attributable to the 1998 restructuring of AMI. … Domestic sales growth was 21%, including a six point increase attributable to the restructuring of AMI, while foreign sales grew 8% including a two percentage point unfavorable effect from exchange. The unit volume growth from sales of Merck human health products was driven by established products, including Zocor and Prinivil, as well as newer products, including Fosamax, Cozaar, Hyzaar, Singulair, Propecia, Maxalt, Aggrastat and the 1999 launch of Vioxx.

* * *

> With its product profile for strength, safety and once-daily simplicity, Vioxx remains the country's fastest growing prescription arthritis medicine. In the product's first seven months, U.S. physicians wrote more than five million prescriptions.

The 1999 Form 10-K failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. This 1999 Form 10-K, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

(ii) Merck Announces Results Of VIGOR Study, But Conceals Findings Of Cardiovascular Risks Associated With Vioxx

236. On March 27, 2000 Merck issued a press release (the "March 27, 2000 Press Release") entitled "Merck Informs Investigators of Preliminary Results of Gastrointestinal Outcomes Study With Vioxx." The March 27, 2000 Press Release commented upon the results of the VIGOR study previously discussed in this Complaint. In the March 27, 2000 Press Release, Merck stated that according to the VIGOR study results, "[a]mong patients treated with Vioxx, there was a significantly reduced incidence of serious gastrointestinal events compared to patients treated with naproxen." The March 27, 2000 Press Release also made the following materially false and misleading statements and/or omissions of material facts:

> In addition, significantly fewer thromboembolic events were observed in patients taking naproxen in this GI outcomes study, which is consistent with naproxen's ability to block platelet aggregation. This effect on these events had not been observed previously in any clinical studies for naproxen. Vioxx, like all COX-2 selective medicines, does not block platelet aggregation and therefore would not be expected to have similar effects. As a result, Merck is notifying investigators, who are conducting other Merck studies with Vioxx or another investigational medicine in the same class, of protocol amendments to allow the addition of low-dose aspiring where appropriate.
>
> * * *
>
> An extensive review of safety data from all other completed and ongoing clinical trials, as well as the post-marketing experience with Vioxx, showed no indication of a difference in the incidence of thromboembolic events between Vioxx, placebo and comparator NSAIDs.

The March 27, 2000 Press Release and related SEC filings failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. This March 27, 2000 Press Release, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning the VIGOR study data, internal e-mails, non-public communications to Merck from physicians medical scientists. Moreover, the March 27, 2000 Press Release misleadingly and falsely attributed the higher incidence of cardiac events observed in the VIGOR study to the putative cardioprotective characteristics of naproxen.

237. Merck's internal knowledge about the negative cardiovascular and thrombotic effects of Vioxx was expressed in an email message from March 2000 by Defendant Scolnick, then Merck's head of research, saying that a the VIGOR clinical trial of Vioxx had shown Vioxx increased heart risks, or cardiovascular ("CV") events. "The CV events were clearly there," Dr. Scolnick wrote.

238. Merck's internal knowledge about the negative cardiovascular and thrombotic effects of Vioxx were also expressed in an internal email from Dr. Scolnick to a Merck colleague from April 2000 in which Dr. Scolnick admitted his "worry quotient is high" and he was in "minor agony" about his fears that Vioxx was causing heart attacks, strokes and other problems.

239. On April 24, 2000, Merck issued a press release (the "April 24, 2000 Press Release") through Reuters News entitled "Update 2 - Merck Profits Rise 15 Percent, Led By Vioxx," in which the Company announced its financial results for the first quarter of 2000. The April 24, 2000 Press Release contained the following materially false and misleading statement and/or omission of material fact:

> Merck & Co., Inc., the No. 1 U.S. drug company, said on Monday its first-quarter net income rose a better-than-expected 15 percent, paced by strong sales of its growing arthritis drug Vioxx.
>
> Merck, which is one of 30 members of the Dow Jones industrial average, said net income rose to $1.5 billion, or 63 cents per share, from $1.3 billion, or 54 cents, in the year-ago quarter.
>
> Analysts, on average, expected the drug maker to earn a profit of 62 cents per share, according to research firm First Call/Thomson Financial.
>
> Sales of Vioxx, its new blockbuster drug, hit $370 million in the quarter. The drug, approved in the United States last May, is indicated for treatment of osteoarthritis and acute pain. It is the second member of a new family of drugs that selectively inhibit the so-called COX-2 enzyme, which has been linked to inflammation, without the severe gastrointestinal problems seen with older drugs.

The April 24, 2000 Press Release failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. This April 24, 2000 Press Release and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning the VIGOR study data, internal e-mails, and non-public communications to Merck from physicians medical scientists.

240. The Company issued another press release on April 28, 2000 entitled "Merck Confirms Favorable Cardiovascular Safety Profile of VIOXX." In this press release, Merck reaffirmed its belief in the "Naproxen Hypothesis" and reiterated the favorable cardiovascular safety profile of Vioxx. Specifically, Merck stated:

> In response to speculative news reports, Merck & Co. today confirmed the favorable safety profile of Vioxx.
>
> In preliminary findings from Merck's large gastrointestinal (GI) study that compared Vioxx in patients with rheumatoid arthritis, significantly fewer heart attacks were observed in patients taking naproxen (0.1 percent) compared to patients taking Vioxx (0.5 percent). This result is consistent with naproxen's ability to block platelet aggregation. This is the first time this effect of naproxen to reduce these events has been demonstrated in a clinical study. Vioxx, like all COX-2 selective medicines, does not block platelet aggregation and therefore would not be expected to have these effects in reducing these events.

> Extensive review of data from the completed osteoarthritis trials and ongoing clinical trials with Vioxx, as well as post-marketing experience with Vioxx have shown ***NO DIFFERENCE*** in the incidence of cardiovascular events, such as heart attacks, among patients taking Vioxx, other NSAIDs, and placebo.

(Emphasis in original.) The April 28, 2000 press release was materially false and misleading because it failed to disclose material adverse information known to Merck and the Individual Defendants and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability. In addition, the press release was materially false and misleading because it constitutes an affirmatively false misrepresentation that Merck and the Individual Defendants believed in good faith in the "Naproxen Hypothesis" (rather than Vioxx's prothrombotic effects) that was the most likely explanation of the adverse cardiovascular results observed in VIGOR, and failed to disclose that Merck and the Individual Defendants actually believed that Vioxx caused adverse cardiovascular events. The April 28, 2000 press release was further materially false and misleading because it failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning the VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

241. On May 12, 2000, the Company filed with the SEC a Form 10-Q (the "First Quarter 2000 Form 10-Q") signed by Defendant Frazier. The First Quarter 2000 Form 10-Q stated in pertinent part:

> Five key products -- 'Vioxx', 'Zocor', 'Fosamax', 'Singulair' and 'Cozaar'/'Hyzaar'-- led Merck's growth, and now account for more than 50% of Merck's worldwide human health sales. …

> 'Vioxx' remains the fastest growing prescription arthritis medicine in the United States. More than 9 million prescriptions have been written for 'Vioxx' since its U.S. introduction 10 months ago. In addition, it is the only medicine specifically inhibiting COX-2 that is indicated both for treatment of osteoarthritis and for relief of acute pain, such as pain following knee, hip replacement and dental surgery. 'Vioxx' is enjoying strong success in the European countries where it has been launched, including the United Kingdom, Germany and Spain. In all, 'Vioxx' has been launched in more than 50 countries.
>
> Merck is conducting extensive clinical studies with 'Vioxx' to evaluate its efficacy in the treatment of rheumatoid arthritis and in the prevention and treatment of Alzheimer's disease. Merck has also begun studies to investigate whether 'Vioxx' can reduce the number of colon polyps in patients who suffer from them – a broad population at risk of developing colon cancer.

The First Quarter 2000 Form 10-Q failed to disclose material adverse information known to Merck and the Individual Defendants concerning cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability.

242. On May 24, 2000, Merck provided a formal presentation of the VIGOR study data at a major gastrointestinal disease medical conference. Once again, Merck publicly endorsed the "Naproxen Hypothesis" while affirming the good cardiovascular safety profile of Vioxx. In the wake of this presentation, the business analyst community reacted favorably, issuing reports that repeat the likely truth of the "Naproxen Hypothesis." For instance, a May 24, 2000 JP Morgan report states that the adverse cardiovascular results in VIGOR were "probably" due not to prothrombotic risks associated with Vioxx, but rather to naproxen's anti-platelet effect); a May 25, 2000 Morgan Stanley Dean Witter report claimed that Vioxx's "long-term safety profile" was confirmed; and a June 13, 2000 Bernstein Research Call report observes that physicians seem to have subscribed to the "Naproxen Hypothesis," thus improving Vioxx's market outlook, and thus causing Bernstein Research Call to view Merck securities more favorably.

243. The statements at the May 24, 2000 medical conference failed to disclose material adverse information known to Merck and the Individual Defendants and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, and further constitute materially false and misleading statements because they affirmatively put forth the false statement that Merck and the Individual Defendants believed in good faith that it was the "Naproxen Hypothesis" (as distinguished from Vioxx's prothrombotic effects) that was the most likely explanation for the adverse cardiovascular effects observed in VIGOR. Those statements are further materially misleading because they omit to disclose that Merck and the Individual Defendants actually believed that the use of Vioxx caused adverse cardiovascular events, and the totality of facts on which their belief was based. Consequently, investors including Plaintiffs remained unaware of Merck's actual beliefs concerning Vioxx's prothrombotic effects, and were further materially misled as to the significant risk that Vioxx's real safety profile would jeopardize Vioxx's commercial viability and ability to generate substantial revenue for Merck.

244. On June 29, 2000, Merck issued a press release entitled "Merck Submits sNDA for Vioxx Based on Results of Gastrointestinal Outcomes Study" (the "June 29, 2000 Press Release"), in which the Company announced that it had submitted a Supplemental New Drug Application for Vioxx in order to request labeling changes based on the VIGOR study. The June 29, 2000 Press Release and corresponding SEC filings failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. This June 29, 2000

Press Release and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning the VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

245. On July 24, 2000, Merck issued a press release (the "July 24, 2000 Press Release") entitled "Merck's Earnings Per Share Increased 20% for the Second Quarter 2000." The July 24, 2000 Press Release contained the following materially false and misleading statement and/or omissions of material fact:

> Merck & Co., Inc. today announced that earnings per share for the second quarter of 2000 were $0.73, an increase of 20% over the second quarter of 1999. Second quarter net income increased 16% to $1,721.7 million. Sales for the quarter were $9.5 billion, up 18% from the same period last year.
>
> * * *
>
> "Sales growth for the quarter and the first half of 2000 was led by Vioxx, the other newer and established products and growth from the Merck-Medco Managed Care business," said Raymond V. Gilmartin, chairman, president and chief executive officer. "Strong volume gains in both the domestic and international operations contributed to the second quarter results."
>
> * * *
>
> [Vioxx] remains the world's fastest growing prescription arthritis medicine, with more than 12 million prescriptions written since it was first introduced last year. In addition, Vioxx is the only medicine specifically inhibiting COX-2 that is indicated in the United States both for treatment of osteoarthritis and for relief of acute pain.

> In May, Merck presented results from the 8,000-patient Vioxx Gastrointestinal Outcomes Research (VIGOR) study in which Vioxx reduced the incidence of serious gastrointestinal side effects, such as ulcers and bleeding, by more than 50 percent compared to the nonsteroidal anti-inflammatory drug naproxen. In June, Merck submitted a Supplemental New Drug Application for Vioxx to the U.S. Food and Drug Administration (FDA) to request labeling changes based on the study.
>
> To expand the market for Vioxx, Merck continues clinical trials to determine whether Vioxx is effective in the treatment of rheumatoid arthritis and in the prevention and treatment of Alzheimer's disease. Merck has also begun studies to investigate whether Vioxx can reduce the number of colon polyps in patients who suffer from them – a broad population at risk of developing colon cancer.

The July 24, 2000 Press Release failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. This July 24, 2000 Press Release, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning the VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

246. On or about August 9, 2000, Merck filed a Form 10-Q with the SEC (the "Second Quarter 2000 Form 10-Q") signed by Defendant Frazier, which stated that "[e]arnings per share for the second quarter 2000 were $0.73, an increase of 20% over the second quarter of 1999.

Second quarter net income increased 16% to $1,721.7 million. Sales for the quarter were $9.5 billion, up 18% from the same period last year." The Second Quarter 2000 Form 10-Q reiterated that sales growth for the quarter and the first half of 2000 was led by Vioxx. "Sales of Merck human health products increased 19% and 18% for the second quarter and six months, respectively. Sales of Merck human health products outside of the United States accounted for 37% of Merck human health first half 2000 sales." The Second Quarter 2000 Form 10Q repeated its earlier statement that five key products - Vioxx, Zocor, Cozaar/Hyzaar, Fosamax and Singulair - accounted for over 50% of Merck's worldwide human health sales in the first half of 2000.

247. The Second Quarter 2000 Form 10-Q failed to disclose the VIGOR study's finding that Vioxx increased the risk of heart attack; failed to reflect that Merck's purported explanation for the VIGOR study's cardiovascular findings was contradicted by Merck's internal findings; and failed to disclose that Vioxx presented known cardiovascular and thrombotic risks that threatened the drug's medical and commercial viability.

248. On or about March 23, 2001, Merck filed the Company's Form 10-K (the "2000 Form 10-K") with the SEC, signed by Defendants Gilmartin, and Lewent. In the 2000 Form 10-K, Defendants made the following materially false and misleading statements and/or omissions of material fact:

> Vioxx, Merck's newest medicine for the treatment of osteoarthritis and acute pain, has become the world's fastest growing branded prescription arthritis medicine and is already Merck's second largest-selling product. In the United States, Vioxx now accounts for approximately 50% of new prescriptions in the COX-2 class, despite being second to market. Vioxx is the only COX-2 indicated in the United States both for osteoarthritis and acute pain. In May 2000, Merck presented results from an 8,000 patient Vioxx Gastrointestinal Outcomes Research (VIGOR) study, which was subsequently published in the New England Journal of Medicine,

> in which Vioxx reduced the incidence of serious gastrointestinal side effects, such as ulcers and bleeding, by more than 50% compared to the nonsteroidal anti-inflammatory drug naproxen. In June 2000, the Company submitted a supplemental New Drug Application to the FDA to request label changes to reflect the results of this study. In February 2001, an FDA Arthritis Advisory Committee recommended that the gastrointestinal study results, as well as data on certain cardiovascular events, be included in the labeling; the FDA is not obligated to accept the recommendations of its advisory committees. In November 2000, another study showed that Vioxx significantly reduced moderate-to-severe acute pain caused by dental surgery to a greater degree compared to codeine combined with acetaminophen. Merck continues to conduct clinical trials with Vioxx to evaluate its efficacy in the treatment of rheumatoid arthritis and the prevention and treatment of Alzheimer's disease as well as investigating whether Vioxx can reduce the number of colon polyps in patients who suffer from them – a broad population at risk of developing colon cancer.

The 2000 Form 10-K failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx, which threatened Vioxx's medical and commercial viability.

(iii) Merck Falsely Touts Vioxx's Safety Profile As "Excellent"

249. On September 8, 2000, Merck issued a Press Release (the "September 8, 2000 Press Release") entitled "Merck Confirms Excellent Safety Profile of Vioxx." In the September 8, 2000 Press Release and corresponding SEC filings, the Company made the following materially false and misleading statements and/or omissions of material fact:

> Merck & Co., Inc. confirmed today that a routine report issued by the U.K. regulatory authority demonstrates the excellent safety profile of Vioxx (rofecoxib), Merck's medicine for osteoarthritis.
>
> The report was issued by the U.K. Medicines Control Agency (MCA) because Vioxx has now been available in the U.K. for one year. During that time, more than 550,000 prescriptions for Vioxx were written for patients in the U.K. The events listed were reported by physicians as events that occurred while patients were taking Vioxx, and were not specifically attributed to Vioxx.

> "Merck considers patient safety to be of the utmost importance, and we routinely monitor all of our medicines. What was reported by the MCA confirms what we've seen in the thousands of patients in our controlled clinical trials and in clinical practice: Vioxx has an excellent safety profile," says Eve Slater, M.D. senior vice president, Clinical and Regulatory Development, Merck Research Laboratories.

The September 8, 2000 Press Release and related SEC filings failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. This September 8, 2000 Press Release, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning the VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

250. On October 20, 2000 Merck issued a press release (the "October 20, 2000 Press Release") entitled "Merck's Earnings Per Share Increased 22% for the Third Quarter 2000, Driven by Record Sales of More Than $10 Billion," in which the Company announced its financial results for the third quarter of 2000. The October 20, 2000 Press Release and related SEC filings contained the following materially false and misleading statements, which failed to disclose material facts:

> [E]arnings per share for the third quarter of 2000 were $0.78, up 22% over the third quarter of 1999. For the quarter, net income

> increased 19% to $1,835.9 million driven by sales of $10.6 billion, up 29% over the same period last year.
>
> For the first nine months, earnings per share were $2.15, an increase of 20% over 1999. Net income grew 17% to $5,057.3 million, fueled by a 22% sales increase to $28.9 billion for the first nine months of 2000.
>
> * * *
>
> "We are proud of the achievements of our newest medicine Vioxx which, together with Zocor, Cozaar/Hyzaar*, Fosamax, and Singulair are driving Merck's strong performance," Mr. Gilmartin said. These products accounted for 55% of Merck's worldwide human health sales for the first nine months.

The October 20, 2000 Press Release and related SEC filings failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. This October 20, 2000 Press Release, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning the VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

251. On November 3, 2000, the Company issued a press release (the "November 3, 2000 Press Release") entitled "Vioxx Significantly Reduced Pain After Dental Surgery to a Greater Degree Compared to Codeine with Acetaminophen in New Study." In the November 3, 2000 Press Release, the Company announced the results of a study which showed that "Vioxx

50mg significantly reduced moderate to severe acute pain after dental surgery to a greater degree compared to codeine 60 mg combined with acetaminophen 600 mg." The November 3, 2000 Press Release stated in pertinent part: "Overall, Vioxx was well tolerated in this study, and overall rate of side effects on Vioxx was generally similar to placebo. Significantly fewer patients taking Vioxx experienced side effects than patients taking codeine with acetaminophen." The November 3, 2000 Press Release failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. This November 3, 2000 Press Release, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning the VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

252. On November 13, 2000, Merck filed a Form 10-Q for the third quarter of 2000 (the "Third Quarter 2000 Form 10-Q") with the SEC, signed by Defendant Frazier. The Third Quarter 2000 Form 10-Q repeated the materially false and misleading statements and/or omissions in the October 20, 2000 Press Release and stated in pertinent part:

> The Company's newest medicine, Vioxx, together with Zocor, Cozaar/Hyzaar, Fosamax and Singulair are driving Merck's strong performance. These products accounted for 55% of Merck's worldwide human health sales for the first nine months.

* * *

> Vioxx has now achieved nearly $1.5 billion in sales so far this year – more than $600 million in this quarter alone. A key reason for its success is that Vioxx is the only COX-2 inhibitor approved by the U.S. Food and Drug Administration (FDA) both for osteoarthritis and acute pain.
>
> A pilot study in osteoarthritis comparing Vioxx and celecoxib, a competitive product, presented at the European League Against Rheumatism in June, showed that Vioxx reduced osteoarthritis pain at night and at rest to a greater degree than either celecoxib 200 mg or acetaminophen 4,000 mg.

The Third Quarter 2000 Form 10-Q failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. This Third Quarter 2000 Form 10-Q, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning the VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

(iv) Merck Promotes Vioxx Through Conferences and Meetings

253. On November 15, 2000, Defendant Gilmartin spoke at the Credit Suisse First Boston Annual Healthcare Conference in Phoenix, Arizona. At the conference, Defendant Gilmartin stated:

> For several years we have been saying that our strategy is based on breakthrough research and demonstrating the value of our medicines. It's a successful strategy -- and the evidence of its success continues to build. We have consistently said that our new medicines and our in-line products would have the potential to offset upcoming patent expirations. And we remain on target. . .
>
> Our results this year have provided exceptional evidence of our strength and growth potential. For the third quarter, our five key products -- Vioxx, Zocor, Singulair, Fosamax and Cozaar/Hyzaar --accounted for nearly 60 percent of our worldwide sales, excluding Merck-Medco. This powerful platform -- along with our pipeline -- will drive growth to 2002 and beyond.

At the November 15, 2000 conference and in the corresponding Form 8-K filed with the SEC, Defendant Gilmartin failed to disclose material adverse information known to him and the other Merck Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability and the lives and health of all Vioxx users.

254. On December 12, 2000, Merck held its Annual Business Briefing. At the Business Briefing, Defendant Gilmartin stated in pertinent part during his opening remarks:

> In six of the last seven quarters, revenue growth for our pharmaceutical and vaccine businesses worldwide ranked either number one or two within our industry. For the last three consecutive quarters, Merck's revenue growth ranked number one in our industry -- 17 percent, 18 percent and 18 percent again.
>
> * * *
>
> Five of our newer medicines have become our key drivers of growth -- Vioxx, Zocor, Singulair, Fosamax, plus Cozaar and Hyzaar. Together, they now account for nearly 60 percent of global pharmaceutical sales, up from 45 percent a year ago.
>
> * * *
>
> Vioxx has achieved approximately 50 percent of the new prescriptions in the COX-2 class in the U.S. Combined with its strong leadership in Europe, Vioxx is firmly positioned for outstanding worldwide growth.

* * *

> Our performance gives us great confidence that we will continue to meet the challenges facing Merck and the industry. And our strategy for growth -- expanding our lead in cutting-edge science, maximizing our five key growth drivers, and building on the success of Merck-Medco -- will make us even stronger in the future.

255. In his closing remarks at the Annual Business Briefing on December 12, 2000, Defendant Gilmartin stated in pertinent part:

> For 2001, Merck is comfortable with the First Call range of analysts Earnings Per Share estimates of $3.15 to $3.25. For the remainder of this year, we continue to be comfortable with fourth quarter 2000 EPS estimates of $0.73 to $0.76 per share.
>
> Merck is well positioned for the future because of our strategy for growth. As a result, we are secure in our commitment to take the Company to a new level of Performance. All of us continue to believe strongly that Merck will achieve its growth goals and continue providing the best of medicines for people around the world.

256. At no time during the Annual Business Briefing or in the corresponding Form 8-K filed on December 12, 2000, did Defendant Gilmartin or any of the other Merck Defendants discuss the material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including Study 090, undisclosed VIGOR test data or the internal e-mails and documents in which Merck's own scientists concluded that Vioxx caused a significantly increased risk of injury and death.

(v) Analysts Embrace The Defendants' False And Misleading Statements

257. During the time period from January 1, 2000 through December 31, 2000, analysts followed Merck's public statements and announcements closely in connection with

reporting Company developments to investors. Analysts routinely repeated Merck's false and misleading financial information:

- On March 16, 2000, Paine Webber issued a report on Merck. It rated Merck "Attractive," with a target price of $59.81. It further provided: "The key near-term driver for Merck is the success of Vioxx. . . . for which 1,276,000 total prescriptions were written in February. . . .We recently raised our 2000 U.S. revenue assumptions for Vioxx to $1.3 billion. Our 2000 Vioxx assumptions may prove conservative;"

- On April 27, 2000, Credit Suisse First Boston issued a report on Merck. It rated Merck a "Buy," with a target price of $90.00. It further provided: "Vioxx sales continue to climb, reaching $370 million in the first quarter. . . .We have raised our estimates to $1.52 billion in 2000 (from $1.45 billion) and $1.8 billion in 2001 (from $1.7 billion);"

- On May 1, 2000, Bernstein Research Call ("Bernstein") issued a report on Merck entitled, "Vioxx and Vascular Events – Much Ado About Nothing." It rated Merck a "Market Perform," with a price target of $69.50. It further provided: "Vioxx isn't causing vascular events, Naproxen is reducing them. . . .Vioxx is not at risk of being relabeled;"

- On July 13, 2000, Paine Webber issued a report on Merck. It rated Merck as "Attractive," with a target price of $73.38. It further provided: "Vioxx achieved 17.7% new prescription market share, up 0.3% from May. For 2000 our U.S. revenue estimate is $1.34 billion and our worldwide Vioxx forecast to $1.75 billion;"

- On July 25, 2000, Sutro & Co. issued a report on Merck entitled, "Better Than Expected Vioxx Trends Cause Us To Increase Our EPS Projections and Upgrade The Stock To Accumulate." It rated Merck "Accumulate," with a price target of $85.00. It further provided: "Worldwide pharmaceutical sales increased 18% in the quarter. This was importantly due to huge sales of Vioxx. In the quarter, it reached sales of $475 million which exceeded total sales achieved in 1999, following its second quarter launch. We project that Vioxx will achieve worldwide sales of $1.9 billion in 2000, $3.0 billion in 2001 and $4.2 billion in 2002;" and

- On November 16, 2000, UBS issued a report on Merck. It rated Merck a "Buy," with a target price of $91.63. It further provided: "Vioxx continues its exceptional launch with total prescriptions exceeding 2.0 million for the first [week] in October (up over 100% year-over-year). . . . Vioxx achieved 18.7% new prescription market share, up 0.1% from September. Our 2000 U.S. revenue estimate is $1.6 billion and our worldwide Vioxx forecast is $2.05 billion."

258. Each of the statements made from January 1, 2000 through December 31, 2000 concerning Vioxx and Merck's fiscal 1999 or fiscal 2000 sales performance was materially false and misleading when made, because each statement failed to disclose material and statistically significant information known to the Company that Vioxx was associated with cardiovascular and thrombotic events. In this regard, the Merck Defendants failed to disclose information about Vioxx that threatened its medical and commercial viability:

- Merck's unpublished Study 090 concluded Vioxx users were 6 times more likely to have severe cardiovascular and thrombotic events than other users of NSAIDS;

- Internal Merck e-mails authored from 1996 through May 1999 reveal that even before the FDA approved Vioxx for prescription use, Merck knew of the significant Vioxx-related cardiovascular and thrombotic risks;

- Substantial data existed in 1999 that Vioxx was associated with a higher risk of cardiovascular and thrombotic events than other NSAIDs;

- On or about December 16, 1999, Merck had received an FDA Letter admonishing Defendants for misleading the public by using deceptive promotional materials that suggested Vioxx had a superior safety profile to other NSAIDS, which was not demonstrated by substantial evidence;

- The Company could not maintain the positive Vioxx sales results that it was experiencing because of the known risks to Vioxx's medical and commercial viability;

- The Merck Defendants knew that the negative cardiovascular and thrombotic events were not due to the cardioprotective properties of naproxen, but were instead directly attributable to the cardiovascular and thrombotic risks that the Merck Defendants observed, *inter alia*, in Study 090 and VIGOR; and

- Vioxx's safety profile was not "excellent" as the Merck Defendants claimed, but was instead marked by an unacceptably high risk of negative cardiovascular and thrombotic events.

C. 2001 EVENTS AND FALSE AND MISLEADING STATEMENTS AND/OR OMISSIONS

259. In 2001, the Defendants made and/or caused to be issued numerous materially false and misleading statements and/or omissions of material facts.

(i) Merck Previews Year-End 2000 Results

260. On January 23, 2001, Merck issued a press release (the "January 23, 2001 Press Release") entitled "Merck's Earnings Per Share Increased 18% for 2000, Driven by the Strong Momentum of Five Key Products." The January 23, 2001 Press Release stated in pertinent part:

> Merck & Co., Inc. today announced that earnings per share for 2000 were $2.90, an increase of 18% over 1999. Net income grew 16% to $6,821.7 million, fueled by a 23% sales increase to $40.4 billion, for the year.
>
> For the fourth quarter of 2000, earnings per share were $0.75, up 14% over the fourth quarter of 1999. Fourth quarter net income increased 12% to $1,764.4 million driven by sales of $11.5 billion, up 28% over the same period last year.
>
> * * *
>
> "Our results reflect the strength of our growth strategy," Mr. Gilmartin said. "Our five key products, VIOXX, ZOCOR, COZAAR/HYZAAR, FOSAMAX AND SINGULAIR, drove Merck's performance for the year and created a powerful platform for growth." These products accounted for 57% of Merck's worldwide human health sales for 2000 and 61% for the fourth quarter.
>
> * * *

> *Since its extraordinarily successful 1999 launch, VIOXX has become the world's fastest growing branded prescription arthritis medicine, and it is already Merck's second largest-selling medicine. In the United States, VIOXX now accounts for approximately 50 percent of new prescriptions in the COX-2 class, despite being second to market in this class in the United States. VIOXX achieved $2.2 billion in sales for the full year 2000, with $700 million in the fourth quarter.*
>
> A Food and Drug Administration (FDA) Advisory Committee meeting is scheduled for Feb. 8 to review labeling changes Merck has requested based on the strong results of the VIGOR Study. This 8,000-patient gastrointestinal outcomes research study, in which VIOXX reduced the risk of serious gastrointestinal complications by half compared to the NSAID naproxen, was published in November in *THE NEW ENGLAND JOURNAL OF MEDICINE.*

(Emphasis added.)

261. While Defendants offered glowing praise for Vioxx and the drug's importance to Merck's financial results, the January 23, 2001 Press Release and corresponding Form 8-K failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx which threatened Vioxx's medical and commercial viability.

262. Merck's own contemporaneous e-mails demonstrate the falsity of their statements about Vioxx. In a January 31, 2001 email, Defendant Scolnick acknowledged he was "pretty agitated" over questions raised by outside scientists about Merck's explanation concerning the VIGOR study. Merck claimed that the study proved naproxen had a beneficial cardiovascular effect (as opposed to admitting the study proved Vioxx had a negative cardiovascular and thrombotic effect.) In his January 31, 2001 email, Dr. Scolnick wrote to Defendant Gilmartin who was then Chief Executive Officer of Merck that is was "impossible to prove" the Company's theory about the safety of Vioxx. The email was also sent to Defendant Anstice, Merck's top marketing executive.

(ii) Merck Announces The FDA Advisory Committee Meeting To Modify Vioxx Label

263. On February 8, 2001, Merck issued a press release (the "February 8, 2001 Press Release") entitled, "FDA Arthritis Advisory Committee Reviews Merck's Application for Revised Labeling for Vioxx Based on Vioxx Gastrointestinal Outcomes Study." In the February 8, 2001 Press Release, Merck announced that the FDA Advisory Committee had agreed that the skewed results from the VIGOR study presented to the FDA by Merck could be included in the labeling for Vioxx. The February 8, 2001 Press Release made the following materially false and misleading statements:

> Merck is confident that the data presented today support the excellent safety profile of Vioxx, and we look forward to further discussions with the FDA to complete the review of our application to modify the labeling for Vioxx.

The February 8, 2001 Press Release failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. This February 8, 2001 Press Release, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

264. During the public hearing before the FDA Arthritis Advisory Committee ("AAC") on February 8, 2001, Defendant Reicin addressed a panel of the AAC. Defendant Reicin stated to the panel that "when you review the results of VIGOR in isolation you don't know whether the imbalance of cardiovascular events [in VIGOR] was caused by a decrease in events or a platelet-inhibiting NSAID, naproxen, or an increase in events on a COX-2 selective inhibitor," that is, Vioxx. Defendant Reicin stated Merck's belief that "the decreased cardiovascular events with naproxen in VIGOR is consistent with [naproxen's] potent antiplatelet effects." These remarks convinced and reassured the AAC members: for example, Dr. Nigel Harris, chair of the AAC, was quoted in a February 8, 2001 *Bloomberg News* report stating, "Differences in cardiac risk between Vioxx and naproxen appeared to result from a beneficial effect of naproxen, not a danger from Vioxx." This line of reasoning – the "Naproxen Hypothesis" – was becoming the refrain of observers, thanks largely to statements by the Defendants like those of Defendant Reicin to the AAC above. For instance, a February 2, 2001 JP Morgan analyst report referred to "the commonly accepted view that [VIGOR's cardiovascular findings are] likely due to the anti-platelet (i.e., anti-clotting) benefits of naproxen (an NSAID) rather than any risk of Vioxx."

265. The statements at the February 8, 2001 public hearing to the FDA AAC panel failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, and further constitute materially false and misleading statements because they affirmatively put forth the false statement that Merck and the Individual Defendants believed in good faith that it was the "Naproxen Hypothesis" (as distinguished from Vioxx's prothrombotic effects) that was the most likely explanation for the adverse

cardiovascular effects observed in VIGOR. Those statements are further materially misleading because they omit to disclose that Merck and the Individual Defendants actually believed that the use of Vioxx caused adverse cardiovascular events, and the totality of facts on which their belief was based. Consequently, investors including Plaintiffs remained unaware of Merck's actual beliefs concerning Vioxx's prothrombotic effects, and were further materially misled as to the significant risk that Vioxx's real safety profile would jeopardize Vioxx's commercial viability and ability to generate substantial revenue for Merck.

266. On or about February 15, 2001, Merck issued a press release (the "February 15, 2001 Press Release") entitled "Merck Releases Financial Guidance For 2001." In the February 15, 2001 Press Release, Merck announced that sales forecasts for Vioxx for 2001 were $3.0 billion to $3.5 billion. The February 15, 2001 Press Release and corresponding Form 8-K failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. This press release, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the known and significant cardiovascular and thrombotic risks.

267. On or about March 1, 2001, the Company issued its Annual Report to investors (the "2000 Annual Report"). Merck's 2000 Annual Report made, among others, the following materially false and misleading statements:

> Since its extraordinarily successful launch in 1998, *Vioxx*, Merck's once-a-day medicine for osteoarthritis and acute pain, has become the world's fastest growing branded prescription arthritis medicine,

> and it is already our second largest selling medicine overall. *Vioxx* is well positioned globally for long-term market leadership.
>
> * * *
>
> Vioxx, Merck's newest medicine for the treatment of osteoarthritis and acute pain, has become the world's fastest growing branded prescription arthritis medicine and is already Merck's second largest-selling product. In the United States, Vioxx now accounts for approximately 50% of new prescriptions in the COX-2 class, despite being second to market. Vioxx is the only COX-2 indicated in the United States both for osteoarthritis and acute pain. In May 2000, Merck presented results from an 8,000 patient Vioxx Gastrointestinal Outcomes Research (VIGOR) study, which was subsequently published in the New England Journal of Medicine, in which Vioxx reduced the incidence of serious gastrointestinal side effects, such as ulcers and bleeding, by more than 50% compared to the nonsteroidal anti-inflammatory drug naproxen. In June 2000, the Company submitted a supplemental New Drug Application to the FDA to request label changes to reflect the results of this study. In February 2001, an FDA Arthritis Advisory Committee recommended that the gastrointestinal study results, as well as data on certain cardiovascular events, be included in the labeling; the FDA is not obligated to accept the recommendations of its advisory committees. In November 2000, another study showed that Vioxx significantly reduced moderate-to-severe acute pain caused by dental surgery to a greater degree compared to codeine combined with acetaminophen. Merck continues to conduct clinical trials with Vioxx to evaluate its efficacy in the treatment of rheumatoid arthritis and the prevention and treatment of Alzheimer's disease as well as investigating whether Vioxx can reduce the number of colon polyps in patients who suffer from them – a broad population at risk of developing colon cancer.

The 2000 Annual Report failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic

risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

(iii) Merck Touts FDA Approval Of Revised Label For Vioxx

268. On April 10, 2001, Merck issued a press release (the "April 10, 2001 Press Release") entitled "Merck Receives 'Approvable' Letter for Vioxx® from FDA on Application for Revised Labeling Based on Vioxx Gastrointestinal Outcomes Study." The April 10, 2001 Press Release contained the following materially false and misleading statements and omissions of material fact:

> Merck & Co., Inc. today confirmed that it has received an approvable letter from the U.S. Food and Drug Administration for the Company's application for changes to the prescribing information for its osteoarthritis and acute pain medicine Vioxx® (rofecoxib).
>
> * * *
>
> The Company submitted a supplemental new drug application on June 29, 2000, seeking changes to reflect results from the Vioxx Gastrointestinal Outcomes Research (VIGOR) study.
>
> The Company is confident in the comprehensive data that support the excellent gastrointestinal and overall safety profile of Vioxx.

This press release and corresponding SEC filings failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent

liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

269. On April 20, 2001, Merck issued a press release (the "April 20, 2001 Press Release") entitled "Merck's First Quarter Earnings Per Share Increase 13%." In the April 20, 2001 Press Release, Merck made the following materially false and misleading statements and/or omissions of material fact:

> Merck & Co., Inc. today announced that earnings per share for the first quarter of 2001 were $0.71, an increase of 13% over the first quarter of 2000. First quarter net income grew 11% to $1,657.3 million driven by a 28% sales increase for the quarter to $11.3 billion.
>
> "Income growth for the quarter reflects strong worldwide sales volume gains by our five key growth drivers -- ZOCOR, VIOXX, COZAAR AND HYZAAR*, FOSAMAX AND SINGULAIR -- which combined had increased sales of 30% over first quarter 2000 sales," said Raymond V. Gilmartin, chairman, president and chief executive officer.
>
> "Because of the benefits they offer patients and prescribers, each of our five key growth drivers are performing well in the global marketplace," Mr. Gilmartin said. "Together, they have created a powerful platform for growth for our company. And it is this growth that allows Merck to continue its strong investment in research and development, which remains the cornerstone of our success."
>
> * * *
>
> Earlier this month, Merck received an approvable letter from the U.S. Food and Drug Administration (FDA) regarding the company's application for changes to prescribing information for VIOXX based on results from the VIOXX Gastrointestinal

> Outcomes Research (VIGOR) study. An approvable letter is defined by the FDA as a written statement that the FDA will approve the application if specific additional information or material is submitted or specific conditions are met.

The April 20, 2001 Press Release and corresponding Form 8-K falsely described Vioxx as a "key growth driver" when Merck knew Vioxx was defective and falsely suggested that further FDA approvals could be properly obtained in light of the known medical and commercial risks associated with Vioxx. Moreover, the April 20, 2001 Press Release 2001 failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

270. On May 10, 2001, the Company filed its Form 10-Q for the first quarter of 2001 (the "First Quarter 2001 Form 10-Q") with the SEC, signed by Defendant Frazier. In addition to repeating the statements made in the April 20, 2001 Press Release, the First Quarter 2001 Form 10-Q made, among others, the following materially false and misleading statements which omitted to state material facts concerning Vioxx: "Vioxx has become the world's fastest-growing branded prescription arthritis medicine, and it is already Merck's second largest-selling

medicine. Vioxx achieved $485 million in sales for the first quarter 2001." The First Quarter 2001 Form 10-Q failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened the drug's medical and commercial viability.

(iv) Merck Promotes False Cardiovascular Safety Profile Of Vioxx

271. On May 11, 2001, Merck issued a press release (the "May 11, 2001 Press Release") entitled "Merck Confirms Renal Safety Profile Of Rofecoxib." The May 11, 2001 Press Release stated that "in comparative studies between Vioxx, celecoxib and acetaminophen, there were no significant differences in the incidents of renal effects, such as hypertension and edema," and that "in these studies, the incidences of increased blood pressure and lower extremity edema among patients taking Vioxx were similar to those of the comparator [NSAIDs] and there were no significant differences between the active treatment groups." The May 11, 2001 Press Release failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

272. On May 22, 2001, Merck issued a press release (the "May 22, 2001 Press Release") entitled "Favorable Cardiovascular Safety Profile of Vioxx." In the May 22, 2001 Press Release, the Company made the following materially false and misleading statements:

> In response to news and analyst reports of data the Company first released a year ago, ***Merck & Co., Inc. today reconfirmed the favorable cardiovascular safety profile of Vioxx (rofecoxib), its medicine that selectively inhibits COX-2***.

(Emphasis added). The May 22, 2001 Press Release and corresponding SEC filings failed to disclose material adverse information known to the Merck Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability.

273. On June 13, 2001, Merck issued a press release (the "June 13, 2001 Press Release") entitled "In New 28,000-Patient Meta-Analysis of Cardiovascular Events: Event Rates With Vioxx® were Similar to Placebo, Similar to Widely Prescribed NSAIDs Ibuprofen, Diclofenac and Nabumetone; Event Rate was Reduced with Naproxen." The June 13, 2001 Press Release made, among others, the following materially false and misleading statements and/or omissions of material fact:

> The rates of cardiovascular events seen in patients taking Vioxx were similar to those seen with both placebo and with the widely prescribed NSAIDs diclofenac, ibuprofen and nabumetone, while the event rate was lower for naproxen compared to Vioxx, said Alise Reicin, M.D., senior director, Merck Research Laboratories. The meta-analysis was strengthened by the fact that the majority of the data included in it was from studies six months or longer in duration.
>
> Aspirin blocks platelet aggregation by more than 90 percent by binding irreversibly to platelets. *This property is believed to be responsible for its cardioprotective effect. It is reported in the scientific literature that naproxen blocks platelet aggregation by about 90 percent if given every 12 hours at its recommended dose –as provided for in the studies with Vioxx.* This anti-platelet effect of naproxen has not been observed among the other comparator

> NSAIDs; it has been reported that they do not block platelet aggregation in a sustained manner.

(Emphasis added). The June 13, 2001 Press Release and corresponding SEC filing failed to disclose material adverse information known to Merck and the Individual Defendants concerning the risk of cardiovascular and thrombotic events associated with Vioxx that threatened Vioxx's medical and commercial viability. Among other things, the statements attributed to Defendant Reicin directly contradicted e-mails authored by Defendant Scolnick in early 2000 and the results of internal studies like Study 090 with which Reicin was familiar. Reicin's statements concerning the purported cardioprotective effect of naproxen are similarly contradicted by Merck's own documents and materials.

274. On June 22, 2001, Merck issued a press release (the "June 22, 2001 Press Release") entitled "Merck Updates Financial Guidance for 2001." In the June 22, 2001 Press Release, the Company stated that it was comfortable with a range of 2001 earnings per share estimates of $3.12 to $3.18, and a range of second quarter 2001 EPS estimates of $0.77 to $0.79. The June 22, 2001 Press Release quoted Defendant Gilmartin as stating:

> In addition, we are pleased that, in the U.S., VIOXX has achieved new prescription leadership in the coxib class. However, while performing within our projected range, VIOXX is not currently expected to reach the top of its range because of slower than expected penetration of the coxib class into the analgesics and arthritis market. This trend, coupled with the adverse impact of foreign exchange on our overall business, has led us to modify the company's EPS guidance for the second quarter and full year of 2001.

The June 22, 2001 Press Release and corresponding Form 8-K failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based

entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

275. On July 20, 2001, Merck issued a press release (the "July 20, 2001 Press Release") entitled "Merck Announces Earnings Per Share of 78 Cents for Second Quarter 2001." The July 20, 2001 Press Release contained the following materially false and misleading statements and/or omissions of material fact:

> "Income growth for the first six months reflects strong worldwide sales volume gains led by our five key growth drivers, which combined increase 28% over the first six months 2000 sales," said Raymond V. Gilmartin, chairman, president and chief executive officer.
>
> * * *
>
> New scientific data supporting the efficacy and overall safety profile of VIOXX were presented at medical meetings during the quarter. These data included the results of the ADVANTAGE trial, presented at the Digestive Diseases Week conference in May. In this study, fewer patients on VIOXX stopped taking their medicine because of gastrointestinal side effects compared to patients taking naproxen, a commonly prescribed non-steroid anti-inflammatory drug.

The July 20, 2001 Press Release and corresponding Form 8-K failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial

viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists. Significantly, the supposedly "new scientific data" referenced in the release as supporting the overall safety profile of Vioxx was illusory at best. In fact, the Merck Defendants knew long before the announcement that Vioxx presented significant risks to consumers.

276. On August 9, 2001, Merck filed a Form 10-Q (the "Second Quarter 2001 10-Q") with the SEC. Defendant Frazier signed the Second Quarter 2001 Form 10-Q, which made the following false and misleading statements and/or omissions concerning Vioxx:

> Vioxx, a once-a-day medicine, is the only COX-2 selective agent indicated in the United States for both osteoarthritis and acute pain. Since its 1999 launch, 'Vioxx' has become the world's fastest-growing branded prescription arthritis medicine, and it is already Merck's second largest-selling medicine. In 2001, 'Vioxx' achieved new-prescription leadership within the coxib market in the United States, demonstrating that physicians continue to recognize the medicine's benefits to patients. 'Vioxx' achieved $725 million in sales for the second quarter.
>
> New scientific data supporting the efficacy and overall safety profile of 'Vioxx' were presented at medical meetings during the quarter. These data included the results of the ADVANTAGE trial, presented at the Digestive Diseases Week conference in May. In this study, fewer patients on Vioxx stopped taking their medicine because of gastrointestinal side effects compared to

> patients taking naproxen, a commonly prescribed non-steroid anti-inflammatory drug.

The Second Quarter 2001 Form 10-Q 2001 failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

(v) Merck Misrepresents Results Of Its Internal Cardiovascular Data

277. On August 21, 2001, Dow Jones Business News published an article reporting on a *Journal of the American Medical Association* study stating there was some evidence linking Cox-2 inhibitors to cardiovascular events. The article then restated Merck's false statements regarding the safety of Vioxx:

> An analysis of clinical trials suggests a potential increase in the rate of heart attack, stroke and other cardiovascular events among patients treated with Vioxx from Merck & Co. Inc. (MRK) and Celebrex from Pharmacia Corp. (PHA) and Pfizer Inc. (PFE), according to an article in *The Journal of the American Medical Association.*
>
> Merck said in a prepared statement it stands behind the overall and cardiovascular safety profile and the favorable gastrointestinal profile of Vioxx. The Company further contended, *"**Extensive***

> ***cardiovascular data already exist on Vioxx and that these data, which weren't incorporated into the authors' analysis, suggest that there is no increase in the risk of cardiovascular events as a result of treatment with Vioxx."***

(Emphasis added). The foregoing statements failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

278. In another August 21, 2001 news report, in *Bloomberg News*, Merck's Senior Director of Cardiovascular Clinical Research, Dr. Laura Demopoulos, anticipating the JAMA study referenced above, is quoted as saying: "We [i.e., Merck] already have additional data beyond what they cite, and ***the findings are very, very reassuring***. VIOXX does not result in any increase in cardiovascular events compared to placebo." (Emphasis added.) The foregoing statements failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the

time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

279. On August 21, 2001, the Company issued a press release (the "August 21, 2001 Press Release") entitled "Merck Stands Behind the Cardiovascular Safety Profile of Vioxx," which stated in relevant part:

> Merck & Co., Inc. today, said the Company stands behind the overall and cardiovascular safety profile and the favorable gastrointestinal (GI) profile of Vioxx. Merck believes Vioxx is an appropriate and efficacious therapy for the relief of the signs and symptoms of osteoarthritis and the management of acute pain in adults.
>
> * * *
>
> The authors [of the *JAMA* article] say that more data are needed on the cardiovascular profile of COX-2 inhibitors. However, Merck believes that extensive cardiovascular data already exist on Vioxx and that these data -- which were not incorporated into the author's analysis -- suggest that there is no increase in the risk of cardiovascular events as a result of treatment with Vioxx.

The August 21, 2001 Press Release failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not

limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists. The August 21, 2001 Press Release -- apparently designed to falsely reassure both patients and investors that Vioxx was safe and commercially viable -- directly contradicted Merck internal documents that demonstrated conclusively the statistically significant risks known to the Merck Defendants even before Vioxx was introduced.

(vi) Merck Refutes Statements In September 17, 2001 FDA Letter

280. On September 24, 2001, Reuters published an article entitled "Merck Vioxx Promotions Said Misleading on Safety," in which it described a September 17, 2001 FDA letter. The September 24, 2001 article quoted Merck spokeswoman Christine Fanelle, who stated that the Company was developing a response to the FDA that it planned to submit by October 1, 2001: "We continue to stand behind the overall safety and cardiovascular safety of Vioxx." Fanelle's statements failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

281. On October 9, 2001, an article appearing in the *New York Times* concerning COX-2 inhibitors and the potential cardiovascular risk associated with them, quoted Defendant Scolnick as saying: "[T]here are two possible interpretations [of the cardiovascular results observed in VIGOR]. . . [n]aproxen lowers heart attack rate, or VIOXX raises it. . . Either COX-2 inhibitors shift the clotting balance, or naproxen, which can impede blood clotting, has a positive effect." Defendant Scolnick continued, "[W]hile the Company announced the heart attack findings to doctors and the public, it looked back at its data from studies using different drugs or dummy pills in comparison to VIOXX. It found no evidence that VIOXX increased the risk of heart attacks." Finally, Defendant Scolnick reaffirmed Merck's and the Individual Defendants' belief in the "Naproxen Hypothesis": "[T]he likeliest interpretation of that data is that naproxen lowered the thrombotic event rate."

282. The statements attributed to Defendant Scolnick in the October 9, 2001 *New York Times* article failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, and further constitute materially false and misleading statements because they affirmatively put forth the false statement that Merck and the Individual Defendants believed in good faith that it was the "Naproxen Hypothesis" (as distinguished from Vioxx's prothrombotic effects) that was the most likely explanation for the adverse cardiovascular effects observed in VIGOR. Those statements are further materially misleading because they omit to disclose that Merck and the Individual Defendants actually believed that the use of Vioxx caused adverse cardiovascular events, and the totality of facts on which their belief was based. Consequently, investors including Plaintiffs remained unaware of Merck's actual beliefs concerning Vioxx's prothrombotic effects, and were further materially

misled as to the significant risk that Vioxx's real safety profile would jeopardize Vioxx's commercial viability and ability to generate substantial revenue for Merck.

283. On October 18, 2001, the Company issued a press release (the "October 18, 2001 Press Release") entitled "Merck Announces Third-Quarter Earnings Per Share of 84 Cents," which stated in pertinent part:

> For the first nine months, earnings per share were $2.33, an increase of 8% over the first nine months of 2000. Net income grew 7% to $5,420.9 million over the same period. Sales grew 22% for the first nine months of 2001 to $35.2 billion.
>
> * * *
>
> "Our five key growth drivers, which had increased sales of nearly 30% over the first nine months of 2000 and now account for two-thirds of Merck's worldwide human health sales, continue to lead Merck's income growth," said Raymond V. Gilmartin, chairman, president and chief executive officer. "These products remain a powerful platform for growth, with four of our five key medicines directed at disease categories each having more than 20 million untreated patients in the U.S. alone."
>
> * * *
>
> VIOXX, a once-a-day medicine, is the only COX-2 selective agent approved in the United States for both osteoarthritis and acute pain. Available in more than 70 countries, Vioxx is Merck's second largest-selling medicine. In the third quarter, VIOXX continued new prescription leadership within the coxib market in the United States and in many European and Latin American countries. VIOXX became the first and only coxib approved for acute pain in a European Union country when it launched with that indication in the United Kingdom in September [2001]. In the third quarter, Vioxx achieved $795 million in sales, an increase of 29% over the same quarter last year.
>
> * * *
>
> The Company also noted that four federal lawsuits and a number of state lawsuits, involving individual claims as well as purported class actions, have been filed against the Company with respect to Vioxx. . . . The lawsuits include allegations regarding gastrointestinal bleeding and cardiovascular events. ***The Company***

> ***believes that these lawsuits are completely without merit and will vigorously defend them.***

(Emphasis added). The October 18, 2001 Press Release and related Form 8-K failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

284. On or about November 13, 2001, Merck filed its Form 10-Q for the third quarter 2001 (the "Third Quarter 2001 10-Q") with the SEC, signed by Defendant Frazier, which repeated the positive statements about Vioxx that Merck published in its October 18, 2001 Press Release, but failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew

about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

285. On December 11, 2001, the Company issued a press release (the "December 11, 2001 Press Release") entitled "Merck's Ability to Deliver Breakthrough Medicines Provides Opportunities for Significant Growth Over the Long Term," which discussed the Annual Business Briefing held the same day. The December 11, 2001 Press Release contained the following materially false and misleading statements and/or omissions of material fact:

> Vioxx, Merck's once-a-day COX-2 selective medicine, continues to grow. With its strong efficacy image, VIOXX is the branded product leader within the coxib class for new prescription volume growth year-to-date in the United States. A promising factor for its continued growth is the potential inclusion of safety data from the VIGOR study, currently under FDA review, in the label of VIOXX.

The December 11, 2001 Press Release and related Form 8-K failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

(vii) Analysts Embrace the Defendants' False And Misleading Statements

286. During the time period from January 1, 2001 through December 31, 2001, analysts followed Defendants' public statements and announcements closely in connection with reporting Company developments to investors. Analysts routinely repeated Defendants' materially false and misleading statements, which consistently omitted material facts concerning the cardiovascular risks that Vioxx presented and the continuing threat that such risks posed to Vioxx's medical and commercial viability, and used such statements as the basis for their reports:

- On February 16, 2001, UBS issued a report on Merck. It rated Merck a "Buy," with a price target of $78.10. It further provided: "Merck announced slightly aggressive sales forecasts for its five key growth drivers Vioxx, Zocor, Fosamax, Cozaar/Hyzaar and Singulair. Although our current estimates for these products are in-line with Merck's guidance, we are changing our 2001 worldwide revenue assumption for Vioxx by $225 million to $3.25 billion due to strength in script trends;"

- On March 15, 2001, UBS issued a report on Merck. It rated Merck a "Buy" with a price target of $71.93. It further provided: "Vioxx continues its exceptional launch with over 1.9 million prescriptions in the month (up over 51% year-over-year). . . .This is clearly a very strong number, with the most recent weekly prescriptions annualizing at a run rate of almost $2.2 billion. Our 2001 U.S. revenue assumption for Vioxx is $2.45 billion;" and

- On July 19, 2001, UBS issued a report on Merck. It rated Merck a "Buy," with a target price of $67.55. It further provided: Vioxx continues its exceptional launch with almost 2.2 million prescriptions in the month (up over 24% year-over-year). This is clearly a very strong number, with the most recent weekly prescriptions annualizing at a run rate of almost $2.3 billion. Our 2001 U.S. revenue assumption for Vioxx is $2.3 billion.

287. Each of the statements made from January 2001 through December 2001 concerning Vioxx and Merck's fiscal 2000 and/or fiscal 2001 sales performance was materially false and misleading when made because each statement failed to disclose material facts needed to make the statements made not misleading in light of the circumstances under which they were made. Each of the statements made from January 2001 through December 2001 failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists. The true but concealed and/or misrepresented facts included, but were not limited to:

- Merck's press releases "reconfirming the favorable cardiovascular safety profile of Vioxx" during 2001 were unfounded, because the Merck Defendants knew that Vioxx was associated with high cardiovascular and thrombotic risks;

- Merck's announcements refuting the Cleveland Clinic study results in *JAMA* and stating that the Company stood behind the safety profile of Vioxx were unfounded, as the Merck Defendants were aware that Vioxx in fact caused an increase in adverse cardiovascular and thrombotic events;

- The revised label for Vioxx that Merck announced in April 2001 failed to disclose the severe cardiovascular and thrombotic risks that the Merck Defendants had already observed in, among other things, Study 090 and VIGOR;

- Merck's unpublished Study 090 concluded that Vioxx users were 6 times more likely to have severe cardiovascular events than other users of NSAIDS;

- Internal Merck e-mails authored between 1996 and May 1999 reveal that even before the FDA approved Vioxx for prescription use, Merck knew of the significant Vioxx-related cardiovascular and thrombotic risks;

- Substantial data existed in 1999 that Vioxx was associated with a higher risk of cardiovascular events than other NSAIDs;

- On December 16, 1999, Merck had received the December 16, 1999 FDA Letter admonishing Defendants for misleading the public by using deceptive promotional materials that suggested Vioxx had a superior safety profile to other NSAIDS, which was not demonstrated by substantial evidence;

- The Company could not maintain the positive Vioxx sales results that it was experiencing because of the known risks to Vioxx's medical and commercial viability;

- The Merck Defendants knew that the negative cardiovascular and thrombotic events were not due to the cardioprotective properties of naproxen (a claim for which they had no proof), but were instead directly attributable to the cardiovascular risks that the Merck Defendants observed, *inter alia*, in Study 090; and

- Vioxx's safety profile was not "excellent" as the Merck Defendants claimed, but was instead marked by an unacceptably high risk of negative cardiovascular and thrombotic events.

D. 2002 EVENTS AND FALSE AND MISLEADING STATEMENTS AND/OR OMISSIONS

288. In 2002, the Defendants made and/or caused to be issued numerous materially false and misleading statements and/or omissions of material facts.

(i) Merck Previews Year-End 2001 Results

289. On January 22, 2002, Merck issued a press release (the "January 22, 2002 Press Release") entitled, "Merck's Earnings Per Share Increase 8% for 2001, Driven by the Strong Performance of Five Key Products." In the January 22, 2002 Press Release, the Company made the following materially false and misleading statements which omitted to state material facts concerning Vioxx's safety profile and medical and commercial viability:

> "Our five key growth drivers, which are also our five largest products, now account for 68% of Merck's worldwide human health sales and continue to lead Merck's income growth," said Raymond V. Gilmartin, chairman, president and chief executive officer. These medicines are true breakthroughs -- they offer novel approaches to disease treatment, help large, underserved patient populations and are effective, well-tolerated and convenient. The market-growth potential for these medicines remains strong.
>
> * * *
>
> VIOXX was the product leader in 2001 with the coxib class from prescription volume growth in the United States. Pain relief and gastrointestinal safety continue to be the primary needs in the arthritis and pain market. In December VIOXX was approved for relief of acute pain and pain from dysmenorrhea in 13 member states of the European Union and in Norway and Iceland. For the year, VIOXX achieved $2.6 billion sales, an increase of 18%, with $550 million in the fourth quarter.

Despite identifying Vioxx as a "key growth driver," the Company failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not

limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

290. On or about March 15, 2002, Merck issued its Annual Report to investors (the "2001 Annual Report"). Merck's 2001 Annual Report quoted Defendant Gilmartin as making the following materially false and misleading statements and omissions of material fact concerning Merck's sales figures and Vioxx:

> Just two years after its successful launch, Vioxx, Merck's once-a-day medicine for osteoarthritis and acute pain, had become the world's fastest-growing branded prescription arthritis medicine.
>
> * * *
>
> While our five key growth drivers continued to perform well into the market, the COX-2 class (including Vioxx) experienced lower than expected penetration into the arthritis and analgesics market. This resulted in lower than expected growth for Vioxx, even while it claimed half of new prescriptions in its class. While we remain confident in the continuing worldwide growth potential of Vioxx (prescription trends for the Cox-2 class have been recovering over the past several months), the product's 2001 sales did not meet our expectations.
>
> * * *
>
> Lower than expected sales of Vioxx, the decline in sales of the patent expiration products, and our firm commitment to continue making substantial investments -- about $2.9 billion -- in research and development will impact the Company's performance in 2002.

291. The 2001 Annual Report also made, among others, the following false and misleading statements and omissions of material fact in the "Financial Review" section:

> Vioxx, Merck's second largest-selling product, continued its strong growth in 2001 and was the product leader within the COX-2 class for new prescription volume growth in the United States. It exceeded the $2 billion sales mark faster than any other product in

> Merck's history. Pain relief and gastrointestinal safety continue to be the primary needs in the arthritis and pain market. Vioxx is now available in 68 markets around the world as a once-a-day treatment for osteoarthritis, acute pain and dysmenorrhea and, in some countries outside the United States, rheumatoid arthritis. Physicians are responding favorably to the Company's pain studies in which Vioxx 50 mg was compared to acetaminophen in combination with either codeine 60 mg or oxycodone 5 mg, which are commonly prescribed narcotics. In addition, an initiative with U.S. hospitals resulted in a favorable formulary status for Vioxx at more than 3,000 major hospitals. In November 2001, Vioxx was approved for symptomatic relief in the treatment of adult rheumatoid arthritis in all EU member states through the mutual recognition procedure. In December 2001, Vioxx, under the trade names Ceoxx or Vioxx Acute, was also approved for relief of acute pain and pain from dysmenorrhea in 13 member states of the EU.

Merck's 2001 Annual Report failed to disclose the fact that Merck was maintaining an aggressive campaign of concealment of the Vioxx-related risks at a cost reportedly exceeding $500 million in promotional advertising and litigation expenses. Merck also failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

292. On March 21, 2002, Merck filed its Form 10-K (the "2001 Form 10-K") with the SEC signed by Defendants Gilmartin, Lewent, and Scolnick. The 2001 Form 10-K repeated the false and misleading statements concerning Vioxx that the Company made in its 2001 Annual Report. The 2001 Form 10-K failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. This 2001 Form 10-K, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

(ii) Merck Promotes New Changes To Vioxx's Label While Affirmatively Concealing The Significant Medical And Commercial Risks Associated With Vioxx

293. On April 11, 2002, the Company issued a press release (the "April 11, 2002 Press Release") entitled "Merck Re-Issues New Release for Vioxx -- rofecoxib -- With Prescribing Information Attached." The April 11, 2002 Press Release described a conference call held that day by Merck for pharmaceutical industry analysts, during which Merck re-released the announcement of FDA-approved changes to the label for Vioxx. The April 11, 2002 Press Release stated in pertinent part:

> Vioxx is now the first and only medicine that selectively inhibits the COX-2 enzyme that is proven to reduce the risk of developing clinically important gastrointestinal (GI) side effects in patients with or without risk factors for such GI side effects compared to the non-steroidal anti-inflammatory drug (NSAID) naproxen. In VIGOR, Vioxx 50 mg -- a dose two-times the highest recommended chronic dose -- significantly reduced serious GI side effects, including perforations, obstructions, ulcers and bleeds, by 54 percent compared to a commonly used dose of naproxen (1,000 mg) in rheumatoid arthritis patients. The GI safety benefit compared to naproxen, as shown in VIGOR, now appears as a modification to the GI Warning section of the prescribing information, a section included in the prescribing information for all NSAIDs, including those that selectively inhibit COX-2.
>
> * * *
>
> "Merck is confident in the efficacy and safety profile of Vioxx. VIGOR was a rigorous test of the GI safety of Vioxx versus naproxen and based on that study, the FDA has approved a modification to the standard GI warning section. Our label now reads: 'Although the risk of GI toxicity is not completely eliminated with Vioxx, the results of the VIGOR study demonstrate that in patients treated with Vioxx, the risk of GI toxicity with Vioxx 50 mg once daily is significantly less than with naproxen 500 mg twice daily,'" said Edward M. Scolnick, M.D., executive vice president, science and technology, and president, Merck Research Laboratories, Merck & Co., Inc.

The April 11, 2002 Press Release and corresponding Form 8-K failed to disclose information known to the Merck Defendants indicating that Vioxx presented cardiovascular and thrombotic risks that threatened the medical and commercial viability of the drug. The April 11, 2002 Press Release failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability. This April 11, 2002 Press Release and all similar press releases following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited

to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

294. On April 18, 2002, Merck issued a Press Release (the "April 18, 2002 Press Release") entitled "Merck Announces First-Quarter 2002 Earnings Per Share of 71 Cents." In the April 18, 2002 Press Release, Merck made the following materially false and misleading statements and omissions of material fact:

> Merck & Co., Inc. today announced that earnings per share for the first quarter of 2002 were $0.71, in line with the first quarter of 2001. Net income was $1,625.0 million, compared to $1,657.3 million in the first quarter of last year. Sales were $12.2 billion for the quarter, an increase of 7% compared to the same period last year. Merck's five key growth drivers--ZOCOR, VIOXX, COZAAR AND HYZAAR*, Fosamax and Singular--collectively had increased sales of 23% for the quarter and drove Merck's human health sales performance.
>
> * * *
>
> VIOXX, the Company's second-largest selling medicine, continues to gain acceptance among physicians and patients worldwide. Global sales for the quarter were $650 million. Last week, Merck announced that the FDA has approved changes to the prescribing information for VIOXX, under the gastrointestinal (GI) warning section, to include results from the landmark VIOXX Gastrointestinal Outcomes Research (VIGOR) study. The FDA also approved VIOXX 25 mg for the relief of the signs and symptoms of rheumatoid arthritis in adults.

The April 18, 2002 Press Release failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx sales reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. This April 18, 2002 Press Release, and all similar

press releases following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

295. On April 18, 2002, the *Associated Press Online* published an article (the "April 18, 2002 *AP Online* Article") entitled "Risks of Arthritis Drugs Studied," which stated in pertinent part: "There's growing suspicion that switching from aspirin to a more stomach-friendly arthritis drug could increase some people's risk of heart attacks -- and a study suggests the reason: a drug-caused chemical imbalance that spurs blood clots. . . . Vioxx maker Merck & Co. dismisses the study as irrelevant, because it is in mice and presumes an effect in the human body far larger than the drug actually causes." The April 18, 2002 *AP Online* Article further stated: "But the study looked at mice that had completely inhibited prostacyclin, while cox-2 drugs inhibit the chemical only half as much, said Merck scientist Dr. Alise Reicin. She said the study contributed no new information to the debate, but Merck plans further safety studies to deal with the issue, although she would not provide details." These statements were knowingly and demonstrably untrue when made. Merck did not introduce new studies because it wanted to avoid the likelihood that additional adverse information would come to light.

(iii) Merck Distorts And Discredits Information Highlighting Cardiovascular Risks Associated With Vioxx

296. On May 13, 2002, the Company filed a Form 10-Q (the "First Quarter 2002 Form 10-Q") with the SEC signed by Defendant Frazier. In the First Quarter 2002 Form 10-Q, the

Company restated its announcement that Merck's five key growth drivers had increased sales of 23% for the quarter and drove Merck's human health sales performance. The First Quarter 2002 Form 10-Q also contained the following statement, which was materially false and misleading based upon Defendants' omissions of material fact:

> In a placebo-controlled database derived from two other studies, the number of patients with serious cardiovascular thrombotic events among those receiving 'Vioxx' 25 mg was 21 compared to 35 for patients taking placebo. In these same two placebo-controlled studies, mortality due to cardiovascular thrombotic events was eight versus three for 'Vioxx' versus placebo, respectively. These data also are reflected in the prescribing information. The significance of the cardiovascular findings from these three studies (VIGOR and the placebo-controlled studies) is unknown.
>
> In addition, new data presented at the American Academy of Pain Management meeting in the first quarter showed a single dose of 'Vioxx' 50 mg provided superior pain relief over six hours compared to the narcotic oxycodone 5 mg/acetaminophen 325 mg in patients with moderate to severe pain following dental surgery. 'Vioxx' remains the only medicine that selectively inhibits COX-2 to offer once-daily 24-hour relief for osteoarthritis, rheumatoid arthritis and acute pain.

The First Quarter 2002 Form 10-Q failed to disclose material adverse information known to Merck and the Individual Defendants concerning the risk of cardiovascular events associated with Vioxx, and instead attempted to falsely inform the medical and investment community that the risk of heart attack was higher for patients taking a placebo than for those taking Vioxx. The First Quarter 2002 Form 10-Q failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. This First Quarter 2002 Form 10-Q, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing

contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

297. On July 19, 2002, the Company issued a press release (the "July 19, 2002 Press Release") entitled "Merck Announces Second-Quarter 2002 Earnings Per Share of 77 Cents; Merck's Five Largest Products Collectively Achieve Sales Growth of 14% Over Second-Quarter 2001." The July 19, 2002 Press Release stated in pertinent part:

> "Merck is pleased with the performance of our five key growth drivers and believe that bolstered with new data from clinical outcome trials, these medicines continue to have significant growth potential," said Raymond V. Gilmartin, chairman, president and chief executive officer.
>
> * * *
>
> Global sales of VIOXX, the company's second-largest selling medicine, were $845 million this quarter. In April, the FDA approved changes to the prescribing information to include results from the landmark VIOXX Gastrointestinal Outcomes Research (VIGOR) study and a new indication with VIOXX 25 mg for the relief of the signs and symptoms of rheumatoid arthritis in adults. VIOXX is now the only COX-2 specific inhibitor with a label demonstrating the proven risk reductions in clinically important gastrointestinal events compared to the non-steroidal anti-inflammatory drug (NSAID) naproxen and the only COX-2 specific inhibitor to offer once-daily 24 hour relief for osteoarthritis, rheumatoid arthritis and acute pain.

The July 19, 2002 Press Release, which included statements made by Merck and by Defendant Gilmartin, failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that

threatened Vioxx's medical and commercial viability, including the fact that the Vioxx sales reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. This July 19, 2002 Press Release and all similar press releases and filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

298. On or about August 12, 2002, Defendants Gilmartin, Lewent, and Frazier signed Merck's Form 10-Q for the second quarter of 2002 (the "Second Quarter 2002 Form 10-Q"), which contained the same materially false and misleading statements concerning Vioxx set forth in the Company's July 19, 2002 press release which they knew contradicted Merck's internal findings of Vioxx's significant medical and commercial risks.

299. On October 18, 2002, Merck issued a press release (the "October 18, 2002 Press Release") entitled "Merck Announces Third-Quarter 2002 Earnings Per Share of 83 Cents." The October 18, 2002 Press Release stated in pertinent part:

> Merck's five key growth drivers -- ZOCOR, VIOXX, COZAAR AND HYZAAR*, Fosamax and Singulair -- collectively had increased sales of 8% for the quarter and drove Merck's human health sales performance. Overall, Merck's human health sales in its core pharmaceuticals business were in line with 2001 for the third quarter and first nine months, excluding a 1% benefit and a 1% unfavorable effect from foreign exchange for the third quarter and first nine months, respectively.
>
> * * *

> "We focus on translating cutting-edge science into breakthrough medicine," said Raymond V. Gilmartin, chairman, president and chief executive officer. "The potential of our five largest medicines continues to be demonstrated by results of key clinical outcomes studies. By focusing on what we do best – discovering and developing important new medicines that improve and save people's lives – Merck's growth potential remains strong."
>
> VIOXX, the company's second-largest selling medicine, achieved $755 million in worldwide sales in the third quarter.
>
> Gastrointestinal (GI) safety remains an important consideration when physicians are choosing a medication for the treatment of arthritis. Since the GI outcomes data from the landmark 8,000 - patient VIOXX Gastrointestinal Outcomes Research (VIGOR) study were added to the labeling for VIOXX, the number of key managed care accounts with VIOXX in an advantaged position among coxibs continues to grow. More than 20 million people now have exclusive or preferred access to Vioxx through their managed care plans.

(Emphasis added). Despite the glowing positive statements that Merck and Defendant Gilmartin made concerning Vioxx's efficacy and the drug's impact upon Merck's overall financial performance, the October 18, 2002 Press Release and associated Form 8-K failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx sales reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. This October 18, 2002 Press Release, and all similar statements following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did

not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

300. On November 13, 2002, the Company filed its Third Quarter 2002 Form 10-Q (the "Third Quarter 2002 Form 10-Q") with the SEC, signed by Defendants Gilmartin, Lewent, and Frazier, with certifications signed by Defendants Gilmartin and Lewent stating that the quarterly report did not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which they were made, not misleading with respect to the period covered by the quarterly report. Among other things, the Third Quarter 2002 Form 10-Q stated:

- Merck's five "key growth drivers" had increased sales of 8% for the quarter;
- The Company's gross margin was 37.3% in the 2002 third quarter compared to 40.6% in the 2001 third quarter and 35.7% compared to 39.3% for the respective nine-month periods;
- Vioxx had achieved $755 million in worldwide sales in the third quarter--an increase of 3% over the third quarter 2001;
- Vioxx demonstrated superior efficacy to codeine and oxycodone in acute dental pain studies; and
- Since the GI outcomes data from VIGOR study were added to Vioxx's label, the number of key managed care accounts with Vioxx in an advantaged position among coxibs continued to grow.

While Defendants chose to speak positively concerning Vioxx in the Third Quarter Form 10-Q, they also knowingly and/or recklessly failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the

Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

301. On December 5, 2002, the Company issued a press release (the "December 5, 2002 Press Release") entitled "Merck Announces $3.40 to $3.47 Consolidated Earnings Per Share Range for 2003." The December 5, 2002 Press Release and corresponding Form 8-K stated that "[t]he full year guidance reflects the company's continued expectation for double digit EPS growth in the core pharmaceuticals business." Although the Company's financial forecasts depended upon the continued medical and commercial viability of Vioxx, the December 5, 2002 Press Release failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did

not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

302. On December 10, 2002, the Company issued a press release (the "December 10, 2002 Press Release") entitled "Broadened Portfolio of Breakthrough Medicines Will Drive Merck's Growth," which discussed Merck's presentation to securities analysts at the Company's Annual Business Briefing held the same day. In the December 10, 2002 Press Release, the Company made, among others, the following materially false and misleading statements:

> "Our large in-line franchises -- ZOCOR, *VIOXX*, *FOSAMAX*, *COZAAR/HYZAAR AND SINGULAIR* – are successful because we have demonstrated their clinical benefits to physicians, patients and payors," Mr. Gilmartin added. "Together, these products will drive our growth in 2003. Moving forward, we plan to broaden our portfolio of medicines by expanding our current franchises and moving into new therapeutic categories."

(Emphasis added). The foregoing statement failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

(iv) Analysts Embrace The Defendants' False And Misleading Statements

303. During the time period from January 1, 2002 through December 31, 2002, analysts followed Defendants' public statements and announcements closely in connection with reporting Company developments to investors. Analysts routinely repeated Defendants' materially false and misleading statements, using such statements as the basis for their reports.

304. For example, on April 12, 2002, Morgan Stanley issued a report on Merck which stated:

- We believe the absence of a cardiovascular warning and the relatively benign positioning of the cardiovascular risk removes a significant overhang from the stock;
- [W]e view the relatively benign presentation of the cardiovascular adverse events as positive relative to the market's concerns; and
- MRK's new label reflects Vioxx's superior GI safety profile . . . [which] could well improve MRK's negotiating leverage with managed care.

305. On April 15, 2002, Morgan Stanley issued a report entitled, "Power Brunch with Peter Kim of Merck Research Labs," stating:

- Not surprisingly, Dr. Kim viewed the recent FDA approval of the Vioxx label revision as a favorable event for the franchise; and
- [Dr. Kim] provided a nice summary of . . . Vioxx's superiority on gastrointestinal outcomes and the different rates of cardiovascular events between the two arms of the study. After giving a balanced description of the two hypotheses for the difference in cardiovascular event rates, he emphasized his opinion that the weight of the evidence supports the view that the antiplatelet effects of naproxen provide a cardioprotective benefit and that Vioxx itself does not have a prothrombotic effect. Dr. Kim emphasized the significance of the FDA's allowing the inclusion of the two placebo-controlled studies in the label, as neither of these trials showed a statistically significant difference in

> the rate of cardiovascular events (and actually favored Vioxx on a numerical basis).

306. On April 19, 2002, Morgan Stanley issued a report on Merck. It set Merck at a price target of $72. It further provided:

> All five of the company's core growth drivers exceeded our forecasts, generating growth in the aggregate of 23%. Most notably, Vioxx sales this quarter soared over our forecast, coming in at $650 mm vs. our expectation of $516 mm (U.S. sales: $480 mm; Int'l: $170 mm).

307. On June 14, 2002, UBS Warburg gave Merck a "Buy" and stated:

> Merck sales reps will shortly begin to detail the VIGOR data with the new label (prolonged discussions with the FDA's Division of Drug Marketing, Advertising and Communications), which perhaps could lead to some stabilization or a rebound in Vioxx share.

308. Each of the statements made from January 2002 through December 2002 concerning Vioxx and Merck's fiscal 2001 and/or fiscal 2002 sales performance was materially false and misleading when made because each statement failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from

physicians and medical scientists. The true but concealed and/or misrepresented facts included, but were not limited to:

- At the time of the FDA's February 2001 Advisory Committee meeting, the Merck Defendants were aware of the cardiovascular and thrombotic risks associated with Vioxx, and were aware that Vioxx did not have an excellent safety profile;

- Merck's press releases "reconfirming the favorable cardiovascular safety profile of Vioxx" during 2002 were unfounded, because the Merck Defendants knew that Vioxx was associated with high cardiovascular risks;

- Merck's announcements refuting the Cleveland Clinic study results in *JAMA* and stating that the Company stood behind the safety profile of Vioxx were unfounded, as the Merck Defendants were aware that Vioxx in fact caused an increase in adverse cardiovascular and thrombotic events;

- The revised label for Vioxx that Merck announced in April 2002 failed to disclose the severe cardiovascular and thrombotic risks that the Merck Defendants had already observed in, among other things, Study 090 and VIGOR;

- Merck's unpublished Study 090 concluded that Vioxx users were 6 times more likely to have severe cardiovascular events than other users of NSAIDS;

- Internal Merck e-mails authored between 1996 and May 1999 reveal that even before the FDA approved Vioxx for prescription use, Merck knew of the Vioxx-related medical risks;

- Substantial data existed in 1999 that Vioxx was associated with a higher risk of cardiovascular events than other NSAIDs;

- On December 16, 1999, Merck had received the December 16, 1999 FDA Letter admonishing Defendants for misleading the public by using deceptive promotional materials that suggested Vioxx had a superior safety profile to other NSAIDS, which was not demonstrated by substantial evidence;

- The Company could not maintain the positive Vioxx sales results that it was experiencing because of the known risks to Vioxx's medical and commercial viability;

- Merck Defendants knew that the negative cardiovascular and thrombotic events were not due to the cardioprotective properties of naproxen, but were instead directly attributable to the cardiovascular and thrombotic risks that the Merck Defendants observed, *inter alia*, in Study 090; and

- Vioxx's safety profile was not "excellent" as the Merck Defendants claimed, but was instead marked by an unacceptably high risk of negative cardiovascular and thrombotic events.

E. 2003 EVENTS AND FALSE AND MISLEADING STATEMENTS AND/OR OMISSIONS

309. In 2003, the Defendants made and/or caused to be issued numerous materially false and misleading statements and/or omissions of material facts.

(i) Merck Issues Its 2002 Annual Report

310. On January 28, 2003, Merck issued a press release (the "January 28, 2003 Press Release") entitled "Merck Announces Fourth-Quarter 2002 Earnings Per Share (EPS) of 83 Cents, Full-Year 2002 EPS of $3.14." In the January 28, 2002 Press Release, the Company made the following materially false and misleading statements and/or omissions of material fact:

> VIOXX, Merck's once-a-day coxib, remains the largest and most prescribed arthritis pain medication across many markets worldwide, including Europe, Canada and Latin America. For the year [2002], VIOXX sales grew 8% over 2001 achieving $2.5 billion in sales, with $385 million in the fourth quarter.
>
> New data released in October with respect to VIOXX underscores the proven gastrointestinal (GI) safety profile of VIOXX. An analysis combining data from 20 clinical trials of more than 17,000 arthritis patients presented at the American College of Rheumatology meeting showed that VIOXX significantly reduced by 62 percent the incidence of confirmed upper-GI perforations, ulcers and bleeds compared to four widely used non-selective non-steroidal anti-inflammatory drugs (NSAIDs). The analysis is consistent with the significant reduction of clinically important GI

> events vs. naproxen seen in the landmark 8,000 patient VIOXX Gastrointestinal Outcomes Research (VIGOR) study.

The January 28, 2003 Press Release and corresponding Form 8-K failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

311. On or about January 28, 2003, the Company issued its 2002 Annual Report to investors (the "2002 Annual Report"). Merck's 2002 Annual Report made, among others, the following materially false, and misleading statements and/or omissions of material fact:

> *Vioxx*, Merck's once-a-day coxib, remains the largest and most prescribed arthritis pain medication across many markets worldwide, including Europe, Canada and Latin America. For the year [2002], *Vioxx* sales grew 8% over 2001, achieving $2.5 billion in sales. Excluding the estimated impact of wholesaler buying patterns, the year-on-year growth of Vioxx approximated 1%. In 2003, worldwide sales of coxibs, *Vioxx* and Arcoxia, are expected to approximate $2.6 billion to $2.8 billion.
>
> Pain relief and gastrointestinal (GI) safety remain important considerations when physicians are choosing a medication for the treatment of arthritis. Since the GI outcomes data from the landmark 8,000-patient *Vioxx* Gastrointestinal Outcomes Research (VIGOR) study were added to the labeling for *Vioxx*, the number

> of key managed care accounts with *Vioxx* in an advantaged position among coxibs continues to grow. More than 35 million people now have exclusive or preferred access to *Vioxx* through their managed care plans.
>
> An updated analysis combining data from 20 clinical trials of more than 17,000 arthritis patients was presented at the American College of Rheumatology in the fourth quarter of 2002 and underscores the proven GI safety profile of *Vioxx*. This new data showed that *Vioxx* significantly reduced by 62 percent the incidence of confirmed upper-GI perforations, ulcers and bleeds compared to four widely used non-selective non-steroidal anti-inflammatory drugs (NSAIDs). The analysis is consistent with the significant reduction of clinically important GI events versus naproxen seen in the VIGOR study.

The 2002 Annual Report failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

312. On March 21, 2003, the Company filed a Form 10-K (the "2002 Form 10-K"), signed by Defendants Gilmartin, and Lewent, with certifications by Defendants Gilmartin and Lewent, made pursuant to § 302 of the Sarbanes Oxley Act of 2002, representing that the annual report did not contain any untrue statement of material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such

statements were made, not misleading with respect to the relevant period. The 2002 Form 10-K made the same materially false and misleading statements and omissions of material fact concerning Vioxx that were set forth in Merck's 2001 Annual Report. These statements failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

313. On April 21, 2003, the Company issued a press release (the "April 21, 2003 Press Release") entitled "Merck Announces First-Quarter 2003 Earnings Per Share (EPS) of 76 Cents." The April 21, 2003 Press Release announced that earnings per share for the first quarter of 2003 were $0.76, a 7% increase over the same period in 2002, and consolidated net income was $1,710.4 million, compared to $1,625.0 million in the first quarter of the previous year. In the April 21, 2003 Press Release, the Company made the following materially false and misleading statements and/or omissions of material fact concerning Vioxx:

> Merck's once-a-day coxib, VIOXX, has been launched in 77 countries worldwide. In the United States, VIOXX is the most widely prescribed and frequently preferred coxib on managed care

> formularies. VIOXX is the leading coxib outside the United States. Global sales for the quarter were $527 million.

The April 21, 2003 Press Release and related Form 8-K failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

314. On April 22, 2003, Merck issued a press release (the "April 22, 2003 Press Release") entitled "Merck's Commitment to Research Remains Key to Success, Chairman Tells Stockholders." The April 22, 2003 Press Release stated in pertinent part:

> Merck Continues to Demonstrate the Value of its Medicines
>
> In addition to the development of novel medicines, Merck's major in-line franchises were bolstered by proven outcomes studies over the past year. VIOXX, Merck's once-a-day coxib for the treatment of arthritis and pain, was proven to reduce serious gastrointestinal side effects, including perforations, obstructions, ulcers and bleeds, by 54 percent compared to a commonly used dose of naproxen in rheumatoid arthritis patients.

The April 22, 2003 Press Release and corresponding SEC filings failed to disclose material adverse information known to Merck and the Individual Defendants concerning the

cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

(ii) Merck Refutes Negative Statements Concerning Vioxx's Safety Profile

315. On July 21, 2003, the Company issued a press release (the "July 21, 2003 Press Release") entitled "Merck Announces Second-Quarter 2003 Earnings Per Share -- EPS -- of 83 Cents." The July 21, 2003 Press Release made, among others, the following materially false and misleading statements and/or omissions:

> Merck & Co., Inc. today announced that earnings per share for the second quarter of 2003 were $0.83, an 8% increase over the same period in 2002. Consolidated net income was $1,867.0 million, compared to $1,750.7 million in the second quarter of last year. Consolidated sales grew 4% for the quarter to $13.3 billion
>
> * * *
>
> Merck continues to focus on maximizing the growth of its key products while broadening its portfolio of breakthrough medicines. Sales of ZOCOR, FOSAMAX, COZAAR AND HYZAAR, SINGULAIR AND VIOXX collectively increased 7% for the second quarter of 2003, compared to the second quarter of 2002, and drove Merck's pharmaceutical sales performance, representing 64% of total pharmaceutical sales.

* * *

> Global sales of Merck's first once-a-day coxib, VIOXX, were $801 million during the second quarter. In the United States, Vioxx is the most widely prescribed and frequently preferred coxib on managed care formularies. VIOXX is also the leading coxib outside the United States. Mail-order-adjusted prescription levels in the United States for VIOXX decreased by approximately 7 percent for the quarter. In June, the company increased the price of VIOXX in the United States. In the aggregate, estimated wholesaler buy-in for VIOXX had a favorable impact of $160 million for the quarter. This is expected to have an unfavorable impact on wholesaler purchaser for VIOXX in the remaining quarters of 2003. Estimated wholesaler inventory levels for VIOXX remained within a range customary for Merck product.

The July 21, 2003 Press Release and corresponding Form 8-K failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

316. On August 13, 2003, the Company filed its Form 10-Q for the Second Quarter 2003 (the "Second Quarter 2003 Form 10-Q") with the SEC, signed by Defendant Frazier and containing certifications made pursuant to § 302 of the Sarbanes-Oxley Act of 2002 by Defendants Gilmartin and Lewent, which stated that the report did not contain any untrue

statement of material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances, not misleading with respect to the period covered by the report. The Second Quarter 2003 Form 10-Q, however, failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

317. On October 22, 2003, Merck issued a press release (the "October 22, 2003 Press Release") entitled, "Merck Announces Third-Quarter 2003 Earnings Per Share (EPS) From Continuing Operations of 83 Cents."

318. In the October 22, 2003 Press Release, the Company made the following false and misleading representations and/or omissions:

> Global sales of Merck's first once-a-day coxib, VIOXX, were $510 million during the third quarter and $1.8 billion for the first nine months. In the United States, VIOXX remains the most-widely prescribed and frequently preferred coxib on managed care formularies. More than 85 million prescriptions have been written in the United States since VIOXX was first introduced in 1999.… In the aggregate, estimated wholesaler buy-out for VIOXX had an unfavorable impact of $145 million for the quarter. In 2003,

> worldwide sales of coxibs, VIOXX and ARCOXIA, are expected to approximate $2.5 to $2.7 billion.

The October 22, 2003 Press Release and corresponding Form 8-K failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

(iii) Merck Continues To Tout Vioxx As Safe, Refuting The Results Of A Study Linking Vioxx To Cardiac Events

319. On October 22, 2003, Reuters published an article focusing on Merck's plans to cut over 4,000 jobs, relating this decision to slowing sales of Vioxx. The article, entitled "Merck to Cut 4,400 Jobs, Posts Flat Earnings," reviewed Merck's third quarter 2003 performance and stated, "The arthritis drug [Vioxx] is suffering from clinical trial data suggesting it might slightly raise the risk of heart attacks, and the growing perception that its pain-fighting capabilities are no better than traditional painkillers." The clinical trial to which the article refers was a Merck-sponsored study conducted at Harvard University-affiliated Brigham and Women's Hospital in Boston. On the same day, Credit Suisse First Boston issued an analyst report on Merck informing investors to "[w]atch for [the] upcoming ACR Presentation," that is, the formal

scientific presentation of the Brigham study that the Reuters article mentioned at the American College of Rheumatology conference on October 28, 2003.

320. On October 30, 2003, *The Wall Street Journal* published an article (the "October 30, 2003 Article") entitled "Vioxx Study Sees Heart-Attack Risk -- Merck Funded Research After Concerns Were Raised About Its Painkilling Drug." The article discussed the Brigham study, described above, which found "an increased risk of heart attack, or acute myocardial infarction, compared with patients taking a competing painkiller, Celebrex, from Pfizer Inc. The researchers also found that Vioxx, which has annual sales of $2.5 billion a year, was linked to an increased heart-attack risk compared with patients not taking any painkillers." The October 30, 2003 Article continued:

> The new study, Dr. Topol said, "greatly substantiates our concern about the cardiac side effects." He observed that the possible cardiac effects of Vioxx appear "worse with the higher doses."
>
> Merck discounted the findings. ***"Randomized clinical trials are the gold standard and this isn't such a trial," said Alise Reicin, Merck's executive director of clinical research. "In our placebo-controlled randomized trials, we have found no significant difference between Vioxx and placebo."***

(Emphasis added). Significantly, Defendant Reicin's comments were directly contradicted by her own prior work at Merck, Merck internal documents, e-mails and materials, and Merck's own studies. Reicin's comments also failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and

thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

321. Continuing their aggressive campaign to suppress the truth about Vioxx, Defendants acted quickly to assure Merck's consumers and investors that Vioxx was safe. On November 5, 2003, *The Wall Street Journal* published a Letter to the Editor by Defendant Kim (the "November 5, 2003 *Wall Street Journal* letter") entitled "Merck Stands Behind the Safety of Vioxx." In the November 5, 2003 *Wall Street Journal* letter, Defendant Kim made, among others, the following materially false and misleading representations and/or omissions of material fact:

> Nothing is more important to Merck than the safety of its medicines. Your Oct. 30 story about an observational analysis of Vioxx was incomplete. The article discussed only the findings from this analysis where Vioxx appeared to have an unfavorable risk profile, but failed to report other findings from the same analysis that showed no statistically significant difference in the risk of heart attack for Vioxx compared with other commonly used anti-inflammatory drugs.
>
> The story also failed to report that another observational analysis presented at the same scientific meeting also showed no statistically significant difference in heart attacks between Vioxx and two widely used anti-inflammatory drugs, ibuprofen and diclofenac. *A complete reporting of the data presented might have remedied the mistaken impression left by the story.*
>
> Observational methods lack the rigor of randomized, controlled clinical trials, and have led the scientific community astray before. … That is why observational studies must be interpreted with caution. *Merck stands behind the safety of Vioxx based on the results of numerous randomized, controlled clinical trials.*

(Emphasis added). The November 5, 2003 *Wall Street Journal* Letter failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

322. On November 13, 2003, the Company filed its Form 10-Q (the "Third Quarter 2003 Form 10-Q") with the SEC, signed by Defendant Frazier. The Third Quarter 2003 Form 10-Q contained certifications pursuant to § 302 of the Sarbanes Oxley Act of 2002 by Defendants Gilmartin and Lewent, and certifications pursuant to § 906 of the Sarbanes-Oxley Act of 2002 by Defendant Gilmartin as the Chief Executive Officer, and by Defendant Lewent as the Chief Financial Officer. The Third Quarter 2003 Form 10-Q made the following materially false and misleading statements and/or omissions:

> Global sales of Merck's first once-a-day coxib, VIOXX, were $510 million during the third quarter and $1.8 billion for the first nine months, decreases of 32% and 14% from the comparable prior-year periods. In the United States, VIOXX remains the most-widely prescribed and frequently preferred coxib on managed care formularies.

The Third Quarter 2003 10-Q failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

323. Each of the statements made from January 2003 through December 2003 concerning Vioxx and/or Merck's fiscal 2002 or fiscal 2003 sales performance failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose

concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists. The true but concealed and/or misrepresented facts included, but were not limited to:

- The Defendants were aware that Vioxx created an increased risk of heart attack, and their explanation for the VIGOR study results -- that the Vioxx patients suffered greater incidences of cardiovascular events because of cardioprotective qualities of naproxen -- was false;

- The Company's statements refuting the results of the Brigham and Women's Hospital Study finding an increased risk of heart attack in patients taking Vioxx were unfounded;

- Merck's statements that the lawsuits filed against the Company with respect to Vioxx were meritless were, in fact, unfounded;

- The Defendants' announcement that Merck "stands behind the safety of Vioxx" was unfounded, because Defendants knew that Vioxx, in fact, was associated with significant cardiovascular and thrombotic events and was therefore not safe;

- Merck's press releases "reconfirming the favorable cardiovascular safety profile of Vioxx" during 2003 were unfounded, because Merck knew that Vioxx was associated with high cardiovascular risks;

- Merck's unpublished Study 090 concluded that Vioxx users were 6 times more likely to have severe cardiovascular events than other users of NSAIDS;

- Internal Merck e-mails authored 1996 through May 1999 reveal that even before the FDA approved Vioxx for prescription use, Merck knew of the Vioxx-related significant cardiovascular and thrombotic medical risks;

- Substantial data existed in 1999 that Vioxx was associated with a higher risk of cardiovascular events than other NSAIDs;

- On December 16, 1999, Merck had received the December 16, 1999 FDA Letter admonishing Defendants for

misleading the public by using deceptive promotional materials that suggested Vioxx had a superior safety profile to other NSAIDS, which was not demonstrated by substantial evidence;

- The Company could not maintain the positive Vioxx sales results that it was experiencing because of the known risks to Vioxx's medical and commercial viability;

- Merck Defendants knew that the negative cardiovascular events were not due to the cardioprotective properties of naproxen, but were instead directly attributable to the cardiovascular risks that the Merck Defendants observed, *inter alia*, in Study 090; and

- Vioxx's safety profile was not "excellent" as the Merck Defendants claimed, but was instead marked by an unacceptably high risk of negative cardiovascular and thrombotic events.

F. JANUARY 1, 2004 THROUGH OCTOBER 29, 2004 FALSE AND MISLEADING STATEMENTS AND/OR OMISSIONS

324. From January 1, 2004 through the last day of the Relevant Period, October 29, 2004, the Defendants made and/or caused to be issued numerous materially false and misleading statements and/or omissions of material facts.

(i) Merck Issues Its 2003 Annual Report

325. On January 27, 2004, the Company filed a Form 8-K (the "January 27, 2004 Form 8-K") with the SEC, which attached the January 27, 2004 Press Release as an exhibit. The January 27, 2004 Press Release and associated Form 8-K failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly

increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

326. On or about February 20, 2004, Merck issued its Annual Report to investors (the "2003 Annual Report"). Merck's 2003 Annual Report made, among others, the following materially false and misleading representations and/or omissions of material fact:

> Worldwide sales of VIOXX, Merck's first once-a-day coxib, grew 2% over 2002, achieving $2.5 billion in sales in 2003. Although U.S. mail-order-adjusted prescription levels for VIOXX decreased by approximately 8% in 2003, VIOXX remains the most widely available coxib on managed care formularies in the United States. VIOXX is the only coxib in the United States that offers 24-hour pain relief in a once-daily tablet for all indications, with more than 91 million prescriptions written in the United States since its introduction in 1999. Outside the United States, VIOXX is the bestselling arthritis and pain medicine.
>
> Data presented at the 55th Annual Scientific Meeting of the American Academy of Neurology in April profiled research results for VIOXX in the treatment of acute migraine headaches. VIOXX 25 mg once daily and 50 mg once daily relieved acute migraine pain within two hours and reduced certain symptoms associated with migraine headaches of moderate to severe intensity. VIOXX was well-tolerated compared to placebo in the 557-patient study.

The 2003 Annual Report failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the

introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

(ii) Merck Continues To Reiterate The "Safety" Of Vioxx, Despite Defendants' Knowledge That Vioxx Was In Fact Medically and Commercially Unviable

327. On March 10, 2004, the Company filed a Form 10-K (the "2003 Form 10-K"), signed by Defendants Gilmartin and Lewent, with certifications by Defendants Gilmartin and Lewent, made pursuant to § 302 of the Sarbanes Oxley Act of 2002, representing that the 2003 Form 10-K did not contain any untrue statements of material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the relevant period. The 2003 Form 10-K reiterated the information stated in the 2003 Annual Report, including positive statements concerning Vioxx sales figures and efficacy. The 2003 Form 10-K failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies

conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

328. On March 10, 2004, a *Bloomberg News* report discussing a recent Pfizer study that tended to show Vioxx's connection to increased cardiovascular events was published. In the article, a Merck spokesperson, Mary Elizabeth Blake, characterized the Pfizer study as being "not designed well" and adding that Merck "disagrees with the findings [of the Pfizer study]." These statements failed to disclose material adverse information known to Merck and the Individual Defendants and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, and further constitute materially misleading statements because they imply that Merck and the Individual Defendants believed in good faith that it was the "Naproxen Hypothesis" (as distinguished from Vioxx's prothrombotic effects) that was the most likely explanation for the adverse cardiovascular effects observed in VIGOR. Those statements are further materially misleading because they omit to disclose that Merck and the Individual Defendants actually believed that the use of Vioxx caused adverse cardiovascular events, and the totality of facts on which their belief was based. Consequently, investors including Plaintiffs remained unaware of Merck's actual beliefs concerning Vioxx's prothrombotic effects, and were further materially misled as to the significant risk that Vioxx's real safety profile would jeopardize Vioxx's commercial viability and ability to generate substantial revenue for Merck.

329. On April 22, 2004, the Company issued a press release (the "April 22, 2004 Press Release") entitled "Merck Announces First-Quarter 2003 Earnings Per Share (EPS) of 76 Cents." The April 22, 2003 Press Release announced in pertinent part:

> Merck & Co., Inc. today announced that earnings per share for the first quarter of 2004 were $0.73, a 7% increase over earnings per share from continuing operations in the same period in 2003. Net income was $1,618.6 million, compared to income from continuing operations of $1,545.0 million in the first quarter of last year. Worldwide sales were $5.6 billion for the quarter.
>
> * * *
>
> Worldwide sales of VIOXX, Merck's arthritis and pain medicine, reached $661 million for the first quarter of 2004. U.S. mail-order adjusted prescription levels for VIOXX decreased by 3% during the quarter. In markets outside of the United States, VIOXX continues to be the best-selling arthritis and pain medicine.
>
> On March 26, the FDA approved a supplemental New Drug Application (sNDA) for VIOXX for the acute treatment of migraine attacks with or without aura in adults. Vioxx is the first and only coxib approved to relieve migraine pain and associated migraine symptoms. During the first quarter, the FDA also accepted for filing another sNDA for VIOXX based on studies in juvenile rheumatoid arthritis, and has granted an additional six months of marketing exclusivity in the United States for VIOXX based on that filing. Indications for VIOXX for migraine and juvenile rheumatoid arthritis also are being sought outside of the United States.

Despite the foregoing positive representations concerning Vioxx, the April 22, 2004 Press Release and associated Form 8-K failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the

internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

(iii) Merck Denounces Vioxx Lawsuits As Meritless

330. On May 7, 2004, the Company filed a Form 10-Q (the "May 7, 2004 Form 10-Q") with the SEC, which was signed by Defendant Frazier, and certified pursuant to § 302 of the Sarbanes-Oxley Act of 2002 by Defendants Gilmartin and Lewent. The May 7, 2004 Form 10-Q made the false and misleading representations and/or omissions regarding the federal and state actions against Merck concerning Vioxx: "Litigation is inherently subject to uncertainties and no assurance can be given on the outcome of any given trial. However, the Company believes that these lawsuits are without merit and will vigorously defend against them." The May 7, 2004 Form 10-Q failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

(iv) Merck Removes Name Of Its Co-Author From Study Giving Unflattering Portrait of Vioxx

331. On May 18, 2004, the *American Health Line* published an article (the "May 18, 2004 Article") entitled "Merck: Removes Author's Name from List in Vioxx Study." The May 18, 2004 Article described how when the Harvard-Brigham and Women's Study was originally presented, the list of authors included Merck epidemiologist Dr. Carolyn Cannuscio. However, when the study was published in the online edition of the American Heart Association's journal, *Circulation*, "Cannuscio's name had been removed from the top of the article." The May 18, 2004 article went on to state:

> Study co-author and Harvard medical professor Jerry Avorn said that Harvard, which submitted the final version of the study, removed Cannuscio's name at the request of Merck. "It was definitely not our decision that she be removed as an author," Avorn said, adding, "Our team worked closely with Dr. Cannuscio from the design of the project through the collection and interpretation of the data, and the writing of the paper. She played an active role in all those areas."

332. The May 18, 2004 Article quoted Merck spokesperson May Elizabeth Black as stating:

> "Merck disagreed with the conclusions and didn't think it was appropriate to have a Merck author." Nancy Santanello, Merck executive director of epidemiology and Cannuscio's manager, said that the study had "serious limitations" because it was "not able to control completely for the differences between the groups." Santanello added that Merck is currently conducting research on Vioxx and heart attacks.

The statements attributed to Merck's spokesperson Mary Elizabeth Black were false and misleading because, among other things, she misrepresented the true facts of the Vioxx-related risks and falsely stated that Merck was conducting research on Vioxx and heart attacks.

333. On July 21, 2004, the Company issued a press release (the "July 21, 2004 Press Release") entitled "Merck Announces Second-Quarter 2004 Earnings Per Share (EPS) of 79 Cents."

334. In the July 21, 2004 Press Release, Merck made, among others, the following materially false and misleading representations and/or omissions:

> Merck & Co., Inc. today announced that earnings per share for the second quarter of 2004 were $0.79, level with earnings per share from continuing operations during the same period in 2003. Net income was $1,768.1 million, compared to income from continuing operations of $1.784.5 million in the second quarter of last year. Worldwide sales grew 9% to $6.0 billion for the quarter.
>
> * * *
>
> Worldwide sales of VIOXX, Merck's arthritis and pain medicine, were $653 million for the second quarter and $1.3 billion for the first six months. U.S. mail-order-adjusted prescription levels for Vioxx decreased by 5 percent during the quarter, as compared to the second quarter of 2003.
>
> Following FDA approval for the acute treatment of migraine in late March, VIOXX is now approved for treating more types of painful conditions than any other coxib in the United States and remains the only coxib approved to relieve migraine pain and associated migraine symptoms. Merck continues to seek new uses for Vioxx to extend the clinical benefits of the product to new populations. A supplemental NDA for Vioxx is under review by the FDA for the treatment of juvenile rheumatoid arthritis. Outside of the United States, VIOXX continues to be the best-selling arthritis and pain medicine. Indications for VIOXX for migraine and juvenile rheumatoid arthritis also are being sought outside of the United States.

The July 21, 2004 Press Release and associated Form 8-K failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and

all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists..

335. On August 6, 2004, the Company filed a Form 10-Q (the "August 6, 2004 Form 10-Q") with the SEC, signed by Defendant Frazier and containing certifications made pursuant to § 302 of the Sarbanes-Oxley Act of 2002 by Defendants Gilmartin and Lewent, which stated that the report did not contain any untrue statement of material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances, not misleading with respect to the period covered by the report. In fact, however, the August 6, 2004 Form 10-Q included the same materially false and misleading statements and/or omissions concerning the suits filed against Merck in relation to Vioxx because the August 6, 2004 10-Q falsely stated: ***"The Company believes that these lawsuits are without merit and will vigorously defend against them."*** (Emphasis added.) The August 6, 2004 Form 10-Q failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to

the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

(v) Merck Publicly Discredits Results Of Study By FDA Investigator David Graham

336. On August 25, 2004, *Bloomberg News* published an article (the "August 25, 2004 Bloomberg Article") entitled "Vioxx Raises Heart Risk, Study Says; Merck disputes Tests that Favor Pfizer's Celebrex." The article stated in pertinent part:

> Merck & Co.'s Vioxx painkiller increases the chance of heart attack and death from cardiac arrest more than Pfizer Inc.'s Celebrex, according to a study by a U.S. Food and Drug Administration investigator.
>
> The difference in heart risk was statistically significant between a recommended dose of Vioxx, 25 mg a day or less, and Celebrex, according to results the FDA's David Graham presented at a meeting of the International Society for Pharmacoepidemiology in France.
>
> * * *
>
> "We found that Celebrex appears to be safer from a cardiac perspective at the lower dose," Graham said in a telephone interview from France. "If there's a difference in risk between Celebrex and Vioxx, that's an important public health question, because you have two drugs being used for the same gastrointestinal effect."
>
> * * *
>
> Merck disagrees with the results from Graham and his colleagues, spokeswoman Mary Elizabeth Blake said. Conclusions from that type of examination don't carry as much weight as results from a study comparing two groups of patients actually taking the medicines for a set period of time, she said.

* * *

> Merck researchers and officials have said the difference between Vioxx and other painkillers occurs because a comparison drug, an anti-inflammatory called naproxen, protects the heart. The FDA -- funded study found the contrary -- that naproxen raises heart risk by 18 percent.

The statements attributed to Merck were false when made in that the Merck Defendants knew before the drug was introduced that Vioxx caused serious cardiovascular events.

337. An article dated August 26, 2004 published by the *Associated Press* (the "First August 26, 2004 AP Article") entitled "Merck Disagrees with Vioxx Analysis," stated that "[p]harmaceutical company Merck & Co. 'strongly' disagreed Thursday with the conclusions of a Food and Drug Administration-funded study that said use of the company's arthritis pain reliever Vioxx increased the risk of heart attacks." At the same time, and unbeknownst to the public, Merck used all of its influence with the FDA to attempt to delay and/or thwart publication by Graham of the results of this study.

338. An article dated August 26, 2004 published by the *Associated Press* (the "Second August 26, 2004 AP Article") entitled "Merck Defends Arthritis Drug's Safety After Critical FDA Study," announced that "Merck shares fell 97 cents, or two percent, to $45.05 Thursday," following the release of the FDA study results showing Vioxx's association with a high risk of cardiovascular events. The Second August 26, 2004 AP Article discussed the Company's reaction to the release of the above-described FDA study:

> Pharmaceutical giant Merck & Co. insisted Thursday its blockbuster arthritis drug Vioxx is safe despite new evidence the popular pain pill increases risk of serious heart problems, even death, particularly at high doses.
>
> * * *
>
> Alise Reicin, vice president of clinical research at Whitehouse Station-based Merck, said Vioxx is safe and effective, and

> numerous earlier studies comparing it to a dummy pill found "no difference in the risk of having a serious cardiovascular events." The drug was tested on about 10,000 patients before it went on sale. Reicin said the new study was not as rigorous because it was observational, rather than a controlled experiment in which randomly chosen patients get different treatments and are followed over time.
>
> * * *
>
> Reicin, the Merck research executive, said half of the six observational studies on Vioxx to date found it did not increase heart complications.

Significantly, the statements attributed to Defendant Reicin and to Merck all fail to disclose the significant cardiovascular risks caused by Vioxx -- risks that Defendant Reicin was especially familiar with.

339. An article dated August 26, 2004 published by the *Associated Press* (the "Third August 26, 2004 AP Article") entitled "FDA Voices Concerns Over Arthritis Drug" quoted Defendant Kim's analysis of the above-described study results: "Observational analyses do not have the rigor of randomized, controlled clinical trials. . . . Based on all of the data that are available from our clinical trials, Merck stands behind the efficacy and safety, including cardiovascular safety, of Vioxx." Merck's efforts to refute Graham's study failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies

conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists.

340. On September 8, 2004, the Dow Jones News Service (the "September 8, 2004 Article") published an article entitled: "Merck: FDA OKs Vioxx for Once-Daily Treatment of Juvenile Rheumatoid Arthritis; First and Only COX-2 Specific Inhibitor Approved for Use in Children As Young as Two." The article announced the FDA's approval of Vioxx for the treatment of juvenile rheumatoid arthritis. Merck continued to press for the FDA's approval to prescribe Vioxx for "children as young as two" despite the fact that Merck knew that Vioxx caused serious cardiovascular damage and despite the fact Merck would later withdraw Vioxx from the market during the very month in which it received approval to use this deadly drug on children.

(vi) The Withdrawal Of Vioxx And Merck's Continued Campaign Of Concealment

341. On September 30, 2004, Merck announced that it was withdrawing Vioxx worldwide, citing as its reason the results of the APPROVe trial. However, the results of the APPROVe study were nothing new to Merck. These results were wholly consistent with studies dating back to the 1998 Study 090 and confirmatory VIGOR study in early 2000.

342. Following the announcement, Merck continued to conceal its prior knowledge of the extent of the cardiovascular risks associated with Vioxx. For example, that same day, Merck held a press conference to explain its decision to withdraw Vioxx. Defendant Gilmartin stated during the press conference:

> This morning, Merck is announcing a voluntary worldwide withdrawal of Vioxx, our Cox-2 inhibitor for arthritis and pain. This decision is the result of new data from a three-year placebo controlled study which was designed to evaluate the possible use

> of Vioxx in preventing the recurrence of colon polyps. This study also collected data on the long-term cardiovascular safety of Vioxx. Importantly, in the first 18 months of the study, there is no difference in the risk for heart attack or stroke in patients taking either Vioxx or placebo. Beginning after 18 months, however, the risk of a cardiovascular event did increase among those on Vioxx . . . . . Accordingly, we are voluntarily withdrawing Vioxx effective today. We are taking this action because we believe it best serves the interest of patients. We believe it would have been possible to continue to market Vioxx with labeling that would incorporate this new data. However, given the availability of alternative therapies, and the questions raised by the data, we concluded that a voluntary withdrawal is the responsible course to take.

Gilmartin's statements and the associated SEC filings were wholly false and misleading and were designed to conceal Merck's pre-1999 knowledge of Vioxx's cardiovascular and commercial risks.

343. According to a September 30, 2004 article published by the *Wall Street Journal* Online (the "September 30, 2004 WSJ Online Article"), entitled "US Stocks Down on Merck Vioxx Withdrawal News":

> Stocks tumbled Thursday after pharmaceutical giant Merck rattled Wall Street by announcing a voluntary worldwide withdrawal of its Vioxx arthritis and acute-pain medication and slashing its earnings outlook for the year. Merck, a component of the Dow Jones Industrial Average, is down 26% to $32.25, their lowest level since September 1996, according to Thomson Datastream. A hefty 56.8 million Merck shares changed hands within the first hour of trading, accounting for close to 20% of all volume on the New York Stock Exchange.

344. An article published by *The Washington Post* on October 1, 2004 (the "October 1, 2004 Washington Post Article"), discussing the Vioxx withdrawal, cited to statements made by Defendant Lewent:

> The recall is likely to cut Merck's fourth-quarter sales by more than $700 million and shave 50 to 60 cents off Merck's earnings per share for the year, Chief Financial Officer Judy C. Lewent said at a news conference, according to a copy of her prepared remarks.

345. On November 1, 2004, the *Wall Street Journal* published the above-described article entitled "Warning Signs: Emails Suggest Merck Knew Vioxx's Dangers at Early Stage; As Heart-Risk Evidence Rose, Officials Played Hardball; Internal Message: 'Dodge!'; Company says 'Out of Context'" (the November 1, 2004 WSJ Article"). As described more fully above, the November 1, 2004 WSJ Article detailed, among other things, how even though Defendant Gilmartin expressed that the APPROVe study findings tying Vioxx to heart attacks and strokes were unexpected, internal Merck e-mails, marketing materials and interviews with outside scientists indicated that Merck "fought forcefully for years to keep safety concerns from destroying the drug's commercial prospects."

346. The November 1, 2004 WSJ Article made, among others, the following critical points:

- E-mails by and between Company executives in the mid to late 1990s showed that Merck knew that Vioxx increased the risk of cardiac events, and sought to conceal such financially damaging information;

- The VIGOR results, released in March 2000, showed that Vioxx patients, as compared with those taking naproxen, suffered five times as many heart attacks. In March 2000, Defendant Scolnick e-mailed colleagues that the risk of cardiovascular events associated with Vioxx were "clearly there," and was a "mechanism-based problem," but in a news release Merck offered no hint that anyone at the Company knew that Vioxx itself increased the risk of cardiovascular events. When it published the VIGOR results, Merck stated that the study's findings were consistent with the cardioprotective qualities of naproxen--rather than the increased cardiovascular risks associated with Vioxx;

- When the VIGOR study results were published in the *New England Journal of Medicine*, it stated that among patients studied who were not already at high risk for heart attacks, Vioxx did not show a significant rise in heart attacks;

- A Merck training document entitled "Dodge Ball Vioxx" instructed sales representatives to dodge questions or concerns about the cardiovascular effects associated with Vioxx; and

- Merck attempted to suppress discussion about the VIGOR study results by, among other things, telephoning academics to complain about lectures the Company deemed to be "irresponsibly anti-Merck and specifically anti-Vioxx;" withdrawing financing from seminars at which doctors and academics who were critical of Merck's handling of Vioxx were scheduled to speak, and even filing suit to "correct" publications raising concerns about Vioxx's cardiovascular risks and criticizing Merck's handling of those concerns.

(vii) Analysts Embrace The Defendants' False And Misleading Statements

347. During the time period from January 1, 2004 through October 29, 2004, analysts followed Defendants' public statements and announcements closely in connection with reporting Company developments to investors. Analysts routinely repeated Defendants' materially false and misleading statements, using such statements as the basis for their reports:

- On January 28, 2004, Morgan Stanley issued a report on Merck. The report set Merck's price target at $49.00. It further provided: Vioxx sales were $731 million, up 95%, benefiting from very easy comparisons a year ago, when Vioxx underwent a massive buyout. Sales also benefited from a $40 million buy-in. Foreign sales were up 28%. Full year sales were just over $2.5 billion, down 9% but up 24% overseas;

- On April 22, 2004, Morgan Stanley issued a report on Merck. The report provided: Revenues were right in-line with our projections, coming in at $5.63bn compared with our forecast of $5.64bn. Overall, sales of core products were in-line with or better than our expectations…. The most significant positive product variance was actually Vioxx. . . . sales growth of Vioxx was 30% globally to $661mm, including 28% sales growth in the US;

- On April 23, 2004, Morgan Stanley issued a report on Merck. The report set Merck's price target at $54.00 and provided: [Merck's] sales of core products, [including]

> Vioxx, were inline with or better than our expectations. The report further noted that Vioxx sales were $731 million, up 95%, benefiting from very easy comparisons a year ago, when Vioxx underwent a massive buyout. Sales also benefited from a $40 million buy-in; and
>
> - On July 21, 2004, Morgan Stanley issued a report on Merck. The report noted: Merck's stock was performing better than MS had predicted: Importantly, sales variance being better-than-expected sales across the board for Zocor, Vioxx, Cozaar, and Fosamax.

348. Each of the statements made by Defendants from January 2004 through October 29, 2004 concerning Vioxx and/or Merck's fiscal 2003 or fiscal 2004 sales performance failed to disclose material adverse information known to Merck and the Individual Defendants concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability, including the fact that the Vioxx earnings reported therein were based entirely upon sales of a drug that the Merck Defendants knew at the time was defective. These statements, and all similar filings following the introduction of Vioxx, also failed to disclose the constantly increasing contingent liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about including, but not limited to, the information contained in Study 090 and other internal, unpublished studies conducted by or known of by Merck, the internal results Merck knew but did not disclose concerning undisclosed VIGOR study data, internal e-mails, and non-public communications to Merck from physicians and medical scientists. The true but concealed and/or misrepresented facts included, but were not limited to:

- The Merck Defendants' removal of Dr. Cannuscio's name from the Harvard-Brigham and Women's Study was a deliberate attempt by the Merck Defendants to conceal Vioxx's known cardiovascular and thrombotic risks;
- The Kaiser Permanente study confirmed the results of Study 090 and VIGOR, and thus demonstrated that Vioxx

caused severe adverse cardiovascular and thrombotic events;

- Adequate justification for withdrawing Vioxx from the worldwide markets existed well before September 30, 2004, and the Merck Defendants' attempts to base the withdrawal upon the putative results of the APPROVe study were knowingly false when made;

- The Defendants were aware that Vioxx created an increased risk of heart attack, and that its explanation for the VIGOR study results--that the Vioxx patients suffered greater incidences of cardiovascular events because of cardioprotective qualities of naproxen--was false;

- The Company's statements refuting the results of the Brigham and Women's Hospital Study finding an increased risk of heart attack in patients taking Vioxx were unfounded;

- Merck's statements that the lawsuits filed against the Company with respect to Vioxx were meritless were, in fact, unfounded;

- The Defendant's announcements and press releases stating that "Merck stands behind the safety of Vioxx" were unfounded, because Merck knew that Vioxx, in fact, was associated with significant cardiovascular and thrombotic events and was therefore not safe;

- Merck's press releases "reconfirming the favorable cardiovascular safety profile of Vioxx" during 2004 were unfounded, because the Merck Defendants knew that Vioxx was associated with high cardiovascular and thrombotic risks;

- Merck's unpublished Study 090 concluded that Vioxx users were 6 times more likely to have severe cardiovascular events than other users of NSAIDS;

- Internal Merck e-mails authored from 1996 through May 1999 reveal that even before the FDA approved Vioxx for prescription use, Merck knew of significant Vioxx-related cardiovascular and thrombotic risks;

- Substantial data existed in 1999 that Vioxx was associated with a higher risk of cardiovascular and thrombotic events than other NSAIDs;

- On December 16, 1999, Merck had received the December 16, 1999 FDA Letter admonishing Defendants for misleading the public by using deceptive promotional materials that suggested Vioxx had a superior safety profile to other NSAIDS, which was not demonstrated by substantial evidence;

- The Company could not maintain the positive Vioxx sales results that it was experiencing because of the known risks to Vioxx's medical and commercial viability;

- Merck Defendants knew that the negative cardiovascular events were not due to the cardioprotective properties of naproxen, but were instead directly attributable to the cardiovascular risks that the Merck Defendants observed, *inter alia*, in Study 090; and

- Vioxx's safety profile was not "excellent" as the Merck Defendants claimed, but was instead marked by an unacceptably high risk of negative cardiovascular and thrombotic events.

X. DEFENDANTS FAILED TO DISCLOSE SIGNIFICANT CONTINGENT LIABILITIES THAT THE COMPANY FACED BASED UPON VIOXX'S KNOWN DANGERS

349. Defendants also violated GAAP during the Relevant Period by failing to disclose in Merck's financial statements the contingent liabilities that Defendants faced based upon the known cardiovascular risks that Vioxx posed. Defendants' failure to make such disclosures deceived investors, who lacked information necessary to factor the liabilities that Merck faced into such investors' decisions to purchase Merck securities during the Relevant Period.

350. GAAP – which the SEC and the accounting profession recognize as the rules, conventions, and procedures necessary to define accepted accounting practices at a given time -- requires that a company's financial statements disclose contingencies when it is reasonably possible that the company may incur a loss in connection with such contingency. *See* SFAS No.

5 ¶ 10. When circumstances are such that a loss is reasonably possible, a company's disclosure should: (i) state the basis of the contingency; and (ii) estimate the potential loss or range of loss that such contingency may produce.

351. SEC rules also mandate that "where material contingencies exist, disclosure of such matters shall be provided even though a significant change since year-end may not have occurred." *See* Regulation S-X, 17 C.F.R. § 210.10-01.

352. In addition to the provisions above, GAAP requires that financial statements disclose substantial risks and uncertainties that may affect a company's business operations. *See* SOP No. 94-6, Disclosure of Risks and Uncertainties.

353. Defendants violated the foregoing provisions of GAAP and Regulation S-X because the Company's Relevant Period financial statements failed to disclose that the known cardiovascular risks that Vioxx posed placed the drug's medical and commercial viability under a constant threat, thus exposing Merck to loss contingencies as well as the likelihood that the significant revenues associated with Vioxx were at risk.

354. Rather than make the disclosures required by GAAP and the SEC rules, Defendants falsely assured the Company's Relevant Period investors that Merck's financial statements were prepared in accordance with GAAP.

XI. SCIENTER/FRAUDULENT INTENT

A. GENERAL ALLEGATIONS OF SCIENTER

355. The lack of disclosure of material adverse information concerning the cardiovascular and thrombotic risks associated with Vioxx that threatened Vioxx's medical and commercial viability was a top down strategy perpetuated by the Individual Defendants and other senior managers at Merck. Under this scheme, the Individual Defendants and other Merck employees under their supervision failed to disclose the constantly increasing contingent

liabilities that Merck was incurring to Vioxx users exposed to the significant cardiovascular and thrombotic risks that Merck knew about. The Individual Defendants knew and/or recklessly disregarded that the failure to disclose the constantly increasing liabilities that Merck was incurring to Vioxx users caused Merck's financial results and future growth prospects to be materially misleading.

356. The Individual Defendants were active, culpable, direct, substantial, and primary participants in the fraudulent scheme by virtue of (1) their receipt of information reflecting the cardiovascular and thrombotic risks associated with Vioxx described herein and/or their failure to review information they had a duty to monitor, (2) their actual issuance and control over Merck's materially false and misleading statements, (3) their supervision over employees and actual direction of policies that encouraged the fraud, and (4) their association with the Company which made them privy to confidential information concerning the Company. The Individual Defendants knew or recklessly disregarded the materially false and misleading nature of the information they caused to be disseminated to the investing public. The Individual Defendants also knew or recklessly disregarded that the cardiovascular and thrombotic risks associated with Vioxx that caused Merck's financial statements to be materially false and misleading would adversely affect the integrity of the market for the Company's common stock and would cause the price of the Company's common stock to be artificially inflated. The Individual Defendants acted knowingly or in such a reckless manner as to constitute fraud and deceit upon Plaintiffs.

B. THE INDIVIDUAL DEFENDANTS WERE IN POSITIONS OF ACTUAL CONTROL AND/OR SUPERVISION OF MERCK'S MANIPULATIVE PRACTICES

357. The Individual Defendants directed, knew about or recklessly disregarded the fraudulent practices implemented under their watch. As officers of the Company, Defendants Gilmartin, Lewent, Reicin, Frazier, Scolnick, Anstice, and Kim each knew, or should have

known, and had access to – through direct knowledge or knowledge learned through the supervisory nature of their positions – material non-public adverse information and the decisions concerning Vioxx made at the Company but failed to disclose this information to the Company's investors.

(i) Defendant Gilmartin

358. As Merck's President, Chief Executive Officer and Chairman of the Board of Merck, Defendant Gilmartin spearheaded Merck's launch of Vioxx and steered the failure to disclose material adverse information concerning Vioxx throughout the Relevant Period.

359. Defendant Gilmartin ran Merck's Vioxx operations with the assistance of the other Individual Defendants until May 5, 2005, when he "voluntarily resigned" although he was not due to retire until March 2006. The timing of Gilmartin's announcement is highly suspicious, and plainly suggests an exit strategy to avoid humiliation and blame for the fraud that occurred under his leadership at the Company.

360. Defendant Gilmartin had a tremendous stake in Merck's success and indeed his reputation was intimately connected with the success of the Company and its few blockbuster drugs, including Vioxx. Merck's bonus structure awarded huge bonuses based on Merck's performance.

361. On January 31, 2001, Gilmartin who was then Chief Executive Officer of Merck received an e-mail from Scolnick stating that is was "impossible to prove" the Company's theory about the safety of Vioxx.

362. In November 2004, Gilmartin and Merck granted its upper management so-called "golden parachutes" out of the company if a large deal leads to their dismissal or resignation for "good reason." Under the plan, some high-level employees such as Gilmartin could have received as much as three times their annual base salary and target bonus. By embracing golden

parachutes, Merck bucked the trend of shareholders objecting to such payouts. Such parachutes reward executives for under-performance leading up to a change of control.

(ii) Defendant Lewent

363. As Merck's Senior Vice President and CFO, a position she held for seventeen years, Defendant Lewent knew virtually every fact regarding the Company's financial position. Indeed, Lewent learned information and received direct reports from the individuals she supervised.

364. Lewent was in line for Gilmartin's position and needed Vioxx to be, and to continue to be, a blockbuster drug to advance within the Company.

365. Lewent was a member of Merck's Management Committee, a senior management group which evaluates and makes strategic decisions for the Company. As Merck's executive vice president and chief financial officer, Lewent was responsible for making sure Merck's financial performance met analysts' expectations each quarter during the Relevant Period.

366. After Vioxx was withdrawn from the market, Lewent was awarded a golden parachute.

(iii) Defendant Reicin

367. In 1997, a Merck official, Briggs Morrison, warned that testing Vioxx on patients who did not simultaneously take aspirin would highlight ***"more thrombotic events -- that is, blood clots -- and kill [the] drug."*** (Emphasis added). Morrison recognized the fact that the blood-thinning characteristics of aspirin would, at least theoretically, mitigate the risk of cardiovascular and thrombotic events that Merck even then associated with Vioxx.

368. Responding to this fear, Merck's then Vice President for Clinical Research, Defendant Reicin wrote an e-mail stating that Merck was in a "no-win situation." Dr. Reicin agreed that "***the possibility of increased CV [cardiovascular] events is of great concern***."

(Emphasis added.) In the same email, Dr. Reicin suggested "excluding high risk CV patients" in order to "***decrease the CV event rate so that a difference between the two groups would not be evident***." (Emphasis added.)

369. In 2000, Dr. Eliav Barr, a Merck scientist, initially judged that a woman involved in a Vioxx study had probably died of a heart attack. "Common things being common, the clinical scenario is likely to be MI," Dr. Barr wrote in an e-mail message in November 2000 to Defendant Reicin, the clinical research executive. ("MI" is an abbreviation for myocardial infarction, or heart attack.) Dr. Barr continued, "Certainly, it is not definitive. I just used my clinical judgment."

370. Defendant Reicin quickly responded, "I think this should be called an unknown cause of death." A few hours later, Reicin wrote, "I would prefer unknown cause of death so we don't raise concerns."

371. Reicin was quoted in the June 13, 2001 Press Release which made, among others, the following materially false and misleading statements and/or omissions of material fact:

> ***The rates of cardiovascular events seen in patients taking Vioxx were similar to those seen with both placebo and with the widely prescribed NSAIDs diclofenac, ibuprofen and nabumetone, while the event rate was lower for naproxen compared to Vioxx, said Alise Reicin, M.D., senior director, Merck Research Laboratories***. The meta-analysis was strengthened by the fact that the majority of the data included in it was from studies six months or longer in duration.
>
> Aspirin blocks platelet aggregation by more than 90 percent by binding irreversibly to platelets. *This property is believed to be responsible for its cardioprotective effect. It is reported in the scientific literature that naproxen blocks platelet aggregation by about 90 percent if given every 12 hours at its recommended dose –as provided for in the studies with Vioxx.* This anti-platelet effect of naproxen has not been observed among the other comparator NSAIDs; it has been reported that they do not block platelet aggregation in a sustained manner.

(Emphasis added.)

> The new study, Dr. Topol said, "greatly substantiates our concern about the cardiac side effects." He observed that the possible cardiac effects of Vioxx appear "worse with the higher doses." Merck discounted the findings. "***Randomized clinical trials are the gold standard and this isn't such a trial," said Alise Reicin, Merck's executive director of clinical research. "In our placebo-controlled randomized trials, we have found no significant difference between Vioxx and placebo."***

(Emphasis added.) Significantly, Defendant Reicin's comments were directly contradicted by her own prior work at Merck, Merck internal documents, e-mails and materials, and Merck's own studies.

372. Just a month before Merck withdrew Vioxx, the Second August 26, 2004 AP Article discussed the Company's reaction to the release of the FDA study described above at paragraph 330. Reicin went on the attack again:

> Pharmaceutical giant Merck & Co. insisted Thursday its blockbuster arthritis drug Vioxx is safe despite new evidence the popular pain pill increases risk of serious heart problems, even death, particularly at high doses.
>
> * * *
>
> ***Alise Reicin, vice president of clinical research at Whitehouse Station-based Merck, said Vioxx is safe and effective, and numerous earlier studies comparing it to a dummy pill found 'no difference in the risk of having a serious cardiovascular events.' The drug was tested on about 10,000 patients before it went on sale. Reicin said the new study was not as rigorous because it was observational, rather than a controlled experiment in which randomly chosen patients get different treatments and are followed over time.***
>
> * * *
>
> ***Reicin, the Merck research executive, said half of the six observational studies on Vioxx to date found it did not increase heart complications.***

(Emphasis added.)

373. Significantly, the statements attributed to Defendant Reicin and to Merck all fail to disclose the significant cardiovascular risks caused by Vioxx -- risks that Defendant Reicin was especially familiar with.

(iv) Defendant Frazier

374. Defendant Frazier joined Merck in 1994. He had access to Merck's unpublished 090 study showing an increased risk of cardiovascular problems with Vioxx, yet guided Merck's efforts to downplay the risks by contending the internal data was not "statistically significant" when, in fact, it was. Indeed, the internal data comparing Vioxx to naproxen showed a difference in heart attack rates after just one month of use.

375. Frazier assisted Merck's board in approving golden parachutes for the top 230 managers of the company immediately after Vioxx was withdrawn from the market.

376. Frazier was Merck's General Counsel when Merck applied for a patent in 1998 which attempted to reformulate a way to use Cox-2 inhibitors that would reduce cardiovascular problems Merck knew about. Even though the 1998 patent application indicates Merck knew Vioxx had substantial cardiovascular risks, Merck began marketing Vioxx immediately after the FDA approved the drug in May 1999 and Merck misrepresented the VIGOR study results to claim that although patients taking Vioxx were five times more likely to have heart attacks than individuals using naproxen, Merck claimed without any proof that this was a result of naproxen's "cardio-protective properties" and not any defect in Vioxx. These statements made by Frazier and others at Merck were known to be false when made.

377. In connection with the Merck internal marketing document issued to Vioxx sales personnel in 2000 (the "Dodge Ball Memo"), and which purported to provide its recipients with an "obstacle handling guide," Frazier, as Merck's general counsel, denied that the document was intended to instruct sales representatives to "dodge" the truth about Vioxx's cardiovascular risks.

Instead, as reported in *The Wall Street Journal* on November 15, 2004, Defendant Frazier offered the incredible explanation that "Dodgeball" was a "sales training game" in which the goal was to answer potential sales obstacles appropriately and according to the drug's label. Analogizing Merck's dodgeball scheme to the former TV game show, "Family Feud," Frazier explained that if a team member picked up a "dodge" card, that team was given a "pass." The *Wall Street Journal* article quoted Frazier as saying that the "dodging" of a question referred only to the sales training game – not to questions by physicians in practice. Frazier's explanation is expressly contradicted by the statements of Merck's sales representatives who sold Vioxx during the Relevant Period.

(v) Defendant Scolnick

378. On March 9, 2000, Defendant Scolnick, Merck's Chief of Research, sent an e-mail to Merck executives stating that the VIGOR results showed that cardiovascular events "are clearly there." Acknowledging that Vioxx was at fault, Scolnick stated: "[I]t is a shame but it is a low incidence and it is mechanism-based as we worried it was." The e-mail also stated that Defendant Scolnick wanted to develop all available data before Merck made the VIGOR results public, in order to attempt to show that the cardiac and thrombotic risks were an effect of all COX-2 inhibitors, not just Vioxx. As discussed further herein, for the next four years Merck made no public mention of Dr. Scolnick's conclusion that Vioxx itself was increasing the risk of cardiac and thrombotic events.

379. Indeed, in December 2001, as Merck prepared for its annual meeting with analysts and reporters, Dr. Scolnick got furious about a Wall Street analyst's negative report on Vioxx safety. "[I]f he says this I will boil him in oil at the meeting," Dr. Scolnick wrote to a colleague.

380. In an e-mail, Defendant Scolnick wrote, "This course is just stupid." He further noted, "Small marketing studies which are intellectually redundant are extremely dangerous." In e-mail messages on April 7, 2001, to Dr. Douglas A. Greene, an executive vice president at Merck Research Laboratories, Dr. Scolnick wrote that he was especially angry because the Advantage trial had no scientific purpose.

381. In one e-mail message, Defendant Scolnick said the drug trial that included the woman's death had "put us in a terrible situation." Defendant Scolnick expressed his worry in e-mail messages to other senior Merck scientists that the Advantage results would encourage the FDA to demand that Vioxx's label highlight its cardiac risks. Such a change would have damaged Vioxx's sales, especially because competitor drug Celebrex did not have heart risks prominently displayed on its warning label.

382. Following the withdrawal of Vioxx, news emerged that in 1999, Dr. John Oates, a Vanderbilt University pharmacology professor, wrote to Merck's top scientist, Defendant Scolnick. In the letter, Professor Oates described four patients who had heart attacks or strokes while taking a Cox-2 inhibitor. Neither Merck nor Scolnick ever publicly disclosed the problems revealed to them by Dr. Oates.

383. Following the withdrawal of Vioxx, news emerged concerning an internal email dated February 8, 2001, in which Defendant Scolnick, then president of Merck Research Laboratories, stated his antipathy towards FDA pressure on Merck to put safety warnings on Merck's blockbuster drug, Vioxx. Fearful that an FDA warning would hurt sales, Scolnick fought the FDA. In the February 8, 2001 email, Scolnick wrote to his Vioxx development team, after a Merck presentation to the FDA advisory committee, "You made them look like grade D

high school students." When a Merck employee called the FDA's proposed warning "ugly" in an email, Scolnick responded, "It is ugly cubed. They are bastards."

384. Subsequent to the withdrawal of Vioxx, Defendant Scolnick, former president of Merck Research Laboratories, admitted that Alzheimer's disease patients who took Vioxx in two studies had higher death rates than those on a placebo, but Merck never notified physicians or its sales representatives. Scolnick admitted that Merck should have told doctors prescribing Vioxx about the data in 2001.

385. The two Alzheimer's studies, involving about 2,000 patients, were done to determine whether Vioxx could delay the onset or worsening of the neurological disorder. In one study, 13 people taking Vioxx died, compared with three taking a dummy pill; in the other, 21 Vioxx takers died, versus nine on placebo.

386. Scolnick has testified that he does not know whether the Alzheimer's study data was given to the FDA and admitted no letter was sent to physicians and that data about deaths among Alzheimer's patients was not added to the information card Merck salespeople used to answer doctors' questions. Nor did Merck ever issue a news release or seek to publish the data about the Alzheimer's studies.

387. In a 1999 internal email, Defendant Scolnick derided the FDA. Merck had exerted pressure on the FDA in 1999 to approve Vioxx without a heart-attack warning label. Scolnick wrote that winning the Vioxx label it did (which had no heart-attack warning) was a "miracle."

388. Scolnick's knowledge about the negative cardiovascular and thrombotic effects of Vioxx was expressed in an email message from March 2000 by Defendant Scolnick, then Merck's head of research, saying that a the VIGOR clinical trial of Vioxx had shown Vioxx

increased heart risks, or cardiovascular ("CV") events. "The CV events were clearly there," Dr. Scolnick wrote.

389. Merck's internal knowledge about the negative cardiovascular and thrombotic effects of Vioxx were also expressed in an internal email from Scolnick to a Merck colleague from April 2000 in which Scolnick admitted his "worry quotient is high" and he was in "minor agony" about his fears that Vioxx was causing heart attacks, strokes and other problems.

390. In a January 31, 2001 email, Defendant Scolnick acknowledged he was "pretty agitated" over questions raised by outside scientists about Merck's explanation concerning the VIGOR study. Merck claimed that the study proved naproxen had a beneficial cardiovascular effect (as opposed to admitting the study proved Vioxx had a negative cardiovascular and thrombotic effect). In his January 31, 2001 email, Scolnick wrote to Defendant Gilmartin who was then Chief Executive Officer of Merck that it was "impossible to prove" the Company's theory about the safety of Vioxx.

391. In the April 11, 2002 Press Release Scolnick was quoted as follows:

> ***"Merck is confident in the efficacy and safety profile of Vioxx. VIGOR was a rigorous test of the GI safety of Vioxx versus naproxen and based on that study, the FDA has approved a modification to the standard GI warning section. Our label now reads: 'Although the risk of GI toxicity is not completely eliminated with Vioxx, the results of the VIGOR study demonstrate that in patients treated with Vioxx, the risk of GI toxicity with Vioxx 50 mg once daily is significantly less than with naproxen 500 mg twice daily,'" said Edward M. Scolnick, M.D., executive vice president, science and technology, and president, Merck Research Laboratories, Merck & Co., Inc.***

(Emphasis added.)

(vi) Defendant Anstice

392. Defendant Anstice was a key figure in the false and misleading marketing of Vioxx. Soon after its launch, Anstice stated: "After only 28 weeks on the U.S. market, Vioxx,

the once-a-day, anti-inflammatory COX-2 specific inhibitor (a coxib) to treat the signs and symptoms of osteoarthritis and relieve acute pain, is Merck's biggest, fastest and best prescription drug launch ever." Mr. Anstice also stated, "Vioxx is gaining ground as the coxib of choice, achieving more than 40% of new U.S. prescriptions in its class."

393. In his January 31, 2001 email, Scolnick wrote to Anstice, Merck's top marketing executive, that it was "impossible to prove" the Company's theory about the safety of Vioxx. Anstice was involved in Merck's request to the FDA to put the Vioxx risk information in the "clinical studies" and "precautions" section of the package label, not the more serious "warnings" section. Anstice was also involved in forecasting a $500 million drop in sales for the $2.5 billion a year drug if Merck lost its FDA request and the information landed in the "warnings" section.

(vii) Defendant Kim

394. On April 15, 2002, Morgan Stanley issued a report entitled, "Power Brunch with Peter Kim of Merck Research Labs," stating: "Not surprisingly, Dr. Kim viewed the recent FDA approval of the Vioxx label revision as a favorable event for the franchise."

395. According to the April 15, 2002 Morgan Stanley Report, "Dr. Kim provided a nice summary of . . . Vioxx's superiority on gastrointestinal outcomes and the different rates of cardiovascular events between the two arms of the study. After giving a balanced description of the two hypotheses for the difference in cardiovascular event rates, he emphasized his opinion that the weight of the evidence supports the view that the antiplatelet effects of naproxen provide a cardioprotective benefit and that Vioxx itself does not have a prothrombotic effect. Dr. Kim emphasized the significance of the FDA's allowing the inclusion of the two placebo-controlled studies in the label, as neither of these trials showed a statistically significant difference in the rate of cardiovascular events (and actually favored Vioxx on a numerical basis)."

396. On November 5, 2003, The *Wall Street Journal* published a Letter to the Editor by Defendant Kim (the "November 5, 2003 *Wall Street Journal* letter") entitled "Merck Stands Behind the Safety of Vioxx." In the November 5, 2003 *Wall Street Journal* letter, Defendant Kim made, among others, the following materially false and misleading representations and/or omissions of material fact:

> Nothing is more important to Merck than the safety of its medicines. Your Oct. 30th story about an observational analysis of Vioxx was incomplete. The article discussed only the findings from this analysis where Vioxx appeared to have an unfavorable risk profile, but failed to report other findings from the same analysis that showed no statistically significant difference in the risk of heart attack for Vioxx compared with other commonly used anti-inflammatory drugs.
>
> The story also failed to report that another observational analysis presented at the same scientific meeting also showed no statistically significant difference in heart attacks between Vioxx and two widely used anti-inflammatory drugs, ibuprofen and diclofenac. ***A complete reporting of the data presented might have remedied the mistaken impression left by the story.***
>
> Observational methods lack the rigor of randomized, controlled clinical trials, and have led the scientific community astray before. … That is why observational studies must be interpreted with caution. ***Merck stands behind the safety of Vioxx based on the results of numerous randomized, controlled clinical trials.***

(Emphasis added.)

397. The November 5, 2003 *Wall Street Journal* Letter failed to disclose what Defendant Kim and Merck knew: that Vioxx was in fact associated with serious cardiovascular and thrombotic risks and that these risks threatened Vioxx's medical and commercial viability. More specifically, Defendant Kim and the other Merck Defendants had long before concluded

that Vioxx actually caused severely negative cardiovascular and thrombotic events -- a fact confirmed in internal Merck materials.

398. An article dated August 26, 2004 published by the *Associated Press* (the "Third August 26, 2004 AP Article") entitled "FDA Voices Concerns Over Arthritis Drug" quoted Defendant Kim's analysis of the above-described study results: **"Observational analyses do not have the rigor of randomized, controlled clinical trials. . . . Based on all of the data that are available from our clinical trials, Merck stands behind the efficacy and safety, including cardiovascular safety, of Vioxx."** (Emphasis added.) Criticism of methodology notwithstanding, Merck's efforts to refute Graham's study were wholly unavailing because the findings were completely consistent with all of the information in Merck's files, including the results of the 1998 Study 090, the 2000 VIGOR study, the 2001 JAMA study, the Vanderbilt UnitedHealth Care and Kemper studies and the APPROVe study which was to be terminated about one month later.

C. THE INDIVIDUAL DEFENDANTS' STOCK SALES AND INSIDER SELLING SHOW FRAUDULENT INTENT

399. Certain of the Individual Defendants were also motivated to pursue their fraudulent scheme of failing to disclose material information concerning Vioxx's medical and commercial viability in order to reap personal gains through the sale of the Company's common stock at artificially inflated prices, while in possession of adverse non-public information about the risks associated with the use of Vioxx.

400. On March 10, 2005, *The Associated Press* reported that Defendant Gilmartin "realized $34.8 million from exercising options in 2004, the year in which the company was roiled by the withdrawal of its blockbuster painkiller Vioxx." *The Associated Press* also

reported that Defendant Gilmartin's "total compensation for 2003 was about $3 million, including a $1.58 million salary and $1.4 million bonus."

401. Defendant Gilmartin engaged in sales of Merck common stock during the Relevant Period, selling almost **52%** of the shares he held at just prior to Merck's launch of Vioxx:

402. Defendant Lewent engaged in sales of Merck common stock during the Relevant Period selling more than **52%** of the shares she held prior to the launch of Vioxx.

403. Defendant Frazier engaged in sales of Merck common stock during the Relevant Period, selling almost **76%** of the shares he held just prior to Merck's launch of Vioxx.

404. Defendant Scolnick engaged in the following sales of Merck common stock selling almost **61%** of the shares he held prior to the launch of Vioxx:

Date	Number of Shares Sold	Price per Share	Proceeds	Number of Options Exercised	Exercise Price	Cost of Option Exercise
10/25/00	600	$ 85.00000	$ 51,000.00	600	$ 21.20850	$ 12,725.10
10/25/00	600	$ 85.00000	$ 51,000.00	600	$ 16.25000	$ 9,750.00
10/25/00	180,000	$ 85.00000	$ 15,300,000.00	180,000	$ 18.56250	$ 3,341,250.00
10/25/00	200,000	$ 85.00000	$ 17,000,000.00	200,000	$ 21.18750	$ 4,237,500.00
Total	381,200		**$ 32,402,000.00**	381,200		**$ 7,601,225.10**

405. Defendant Anstice sold almost **73%** of the shares he held as of the beginning of the Relevant Period and options exercised during the Relevant Period.

XII. FRAUD ON THE MARKET

406. At all relevant times, the market for Merck's securities was an efficient market for the following reasons, among others:

a. Merck common stock met the requirements for listing, and was listed and actively traded on the New York Stock Exchange (symbol MRK), a highly efficient and automated market;

b. As a regulated issuer, Merck filed regular reports with the SEC;

c. Merck regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;

d. Merck was regularly followed by numerous securities analysts employed by major brokerage firms headquartered in the United States and overseas who wrote reports that were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace;

e. The material misrepresentations and omissions alleged herein would tend to induce a reasonable investor to misjudge the value of Merck's securities; and

f. Without knowledge of the misrepresented or omitted facts, Plaintiffs purchased or otherwise acquired Merck securities between the time that Defendants made the material misrepresentations and omissions and the time that the truth was revealed, during which time the price of Merck securities was artificially inflated by Defendants' misrepresentations and omissions.

407. As a result of the foregoing, the markets for Merck securities promptly reacted to current information regarding Merck from publicly available sources and reflected such information in the trading price of Merck securities. Under these circumstances, a presumption of reliance applies.

XIII. STATUTORY SAFE HARBOR

408. As alleged herein, Defendants acted with scienter because at the time that they issued public documents and other statements in Merck's name, they knew or recklessly disregarded the fact that such statements were materially false and misleading or omitted material facts. Moreover, the Defendants knew such documents and statements would be issued or disseminated to the investing public; knew that persons were likely to rely upon those misrepresentations and omissions; and knowingly and/or recklessly participated in the issuance

and/or dissemination of such statements and/or documents as primary violators of the federal securities laws.

409. As set forth in detail throughout this Complaint, the Defendants, by virtue of their control over and/or receipt of Merck's materially misleading statements and/or their association with the Company which made them privy to confidential proprietary information concerning Merck, used such information to artificially inflate Merck's financial results. Defendants caused or were informed of, participated in, and knew of the scheme alleged herein to distort and suppress material information pertaining to Vioxx's medical risks and tenuous commercial viability. With respect to non-forward looking statements and/or omissions, Defendants knew and/or recklessly disregarded the falsity and misleading nature of that information, which they caused to be disseminated to the investing public.

410. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the false and misleading statements pleaded in this Complaint because none of the statements pleaded herein are "forward-looking" statements and no such statement was identified as a "forward-looking statement" when made. Rather, the statements alleged herein to be false and misleading by affirmative misstatement and/or omissions of material fact all relate to facts and conditions existing at the time the statements were made. Moreover, cautionary statements, if any, did not identify important factors that could cause actual results to differ materially from those in any putative forward-looking statements.

411. In the alternative, to the extent that the statutory safe harbor does apply to any statement pleaded herein which is deemed to be forward-looking, Defendants are liable for the false forward-looking statements because at the time each such statement was made, the speaker

actually knew and/or recklessly disregarded the fact that forward-looking statements were materially false or misleading and/or omitted facts necessary to make statements previously made not materially false and misleading, and/or that each such statement was authorized and/or approved by a director and/or executive officer of Merck who actually knew or recklessly disregarded the fact that each such statement was false and/or misleading when made. None of the historic or present tense statements made by Defendants was an assumption underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such an assumption underlying or relating to any projection or statement of future economic performance when made nor were any of the projections or forecasts made by the Defendants expressly related to or stated to be dependent on those historic or present tense statements when made.

XIV. LOSS CAUSATION

412. Plaintiffs were damaged as a result of Defendants' fraudulent conduct set forth herein. Between May 21, 1999 and October 29, 2004, Merck and the Individual Defendants carried out a course of conduct that artificially inflated the market price of Merck securities and directly caused the losses incurred by Plaintiffs. The price of Merck's common stock closed at $68.38 on May 20, 1999, one day before the FDA approved Vioxx for prescription use as a pain-killer medication on May 21, 1999. Thereafter, while Defendants repeatedly failed to disclose material information, the price steadily rose, reaching a Relevant Period high of $95 on December 29, 2000.

413. Numerous materially false and misleading statements, as described above, were issued by the Defendants and circulated throughout the market, being disseminated to investment analysts, the business media, and the investing public. Consequently, Plaintiffs purchased Merck securities at artificially inflated prices and suffered economic damages when that inflation was

corrected upon the issuance of partial corrective disclosures revealing Merck's and the Individual Defendants' actual beliefs concerning the prothrombotic properties of Vioxx. Between October 22 and October 30, 2003, the truth concerning the risks associated with Vioxx, which had been misrepresented or fraudulently concealed by Merck and the Individual Defendants, partly emerged. As described more fully above, on October 22, 2003, Reuters reported that Vioxx sales had declined in the third quarter of 2003 because of data "suggesting [Vioxx] might slightly raise the risk of heart attacks, and [because of] the growing perception that Vioxx did not have any greater efficacy than traditional NSAIDs." On the same day, Credit Suisse First Boston issued a report informing investors to "[w]atch for [the] upcoming ACR [i.e., American College of Rheumatology] Presentation," which was the formal scientific presentation of the Merck-sponsored Brigham study results, the same data mentioned by Reuters. That study showed an increased risk of heart attack in patients taking Vioxx compared to patients taking Celebrex or placebo. Following the release of this information, Merck shares fell almost 7% -- more than $3 per share – to close at $45.72 on October 22, 2003. A few days later, on October 30, 2003, an article in the *Wall Street Journal* regarding the Brigham study appeared. The price of Merck stock declined again, by 2.2%, to $43.94 upon this publication. However, due to Merck's and the Individual Defendants' repeated damage control efforts, which included making materially false and misleading statements regarding Vioxx's safety profile and commercial viability, the price of Merck securities remained artificially inflated as the fraud continued well into 2004.

414. On September 30, 2004, Merck disclosed that Vioxx was neither commercially nor medically viable and withdrew Vioxx from the market. Upon news of Merck's disclosure, Merck's shares fell more than $12 from $45.07 to close at $33 per share – a 27% single-day

decline, on trading volume over 27 times the normal volume, from the closing price of $45.07 on September 29, 2004 that reduced Merck's market capitalization by more than $26 billion.

415. Subsequently, as the Defendants fought off attacks on Merck for its failure to disclose for several years its prior knowledge of the material commercial and medical liability Vioxx posed and Merck's and the Individual Defendants' actual disbelief in the "Naproxen Hypothesis," as well as attacks on the integrity of Merck's management, marketing department, and scientists, the price of Merck common stock slid down to $31 per share. On November 1, 2004, the publication of a *Wall Street Journal* article, which included additional facts concerning Merck's campaign of concealment, caused Merck's stock price to drop an additional $3.03, yielding a total Vioxx-related market decline of $37 billion.

XV. PLAINTIFFS' CLAIMS ARE TIMELY

416. Plaintiffs' claims are timely pursuant to the class action tolling doctrine endorsed in *American Pipe & Construction Co. v. Utah*, 414 U.S. 538 (1974), and subsequent decisions. In accordance with the *American Pipe* doctrine, the two-year limitations period and five-year period of "repose" (as it has sometimes been called) in 28 U.S.C. § 1658(b), which apply to Plaintiffs' Exchange Act claims, were tolled from November 6, 2003—the date the initial complaint was filed in the Securities Class Action—until on or about November 1, 2013, when Plaintiffs opted out of the Class. Among other things, both the Tenth Circuit Court of Appeals and the MDL Court have ruled that *American Pipe* tolling applies to statutes of "repose" applicable to federal securities claims. *See Joseph v. Wiles*, 223 F.3d 1155, 1168 (10th Cir. 2000) ("we conclude that *American Pipe* tolling applies to the statute of repose governing [plaintiff]'s action [under Section 11 of the Securities Act of 1933]"); *In re Merck & Co. Sec., Derivative & "ERISA" Litig.*, MDL No. 1658 (SRC), 2012 U.S. Dist. LEXIS 180707, at *44 (D.N.J. Dec. 20, 2012) (agreeing with *Joseph*'s "holding and rationale," the MDL Court held that

"the filing of the first class action complaint, in November 2003, tolled the statutory repose period applicable to [individual plaintiff]'s claims [under Section 10(b) of the Exchange Act]"). In deciding to opt out of the Class and file their own action, Plaintiffs relied on Tenth Circuit precedent, as well as the MDL Court's ruling, as to tolling of the statute of "repose."

417. In light of the foregoing, all of Plaintiffs' claims were tolled, in accordance with the *American Pipe* doctrine, from November 6, 2003 until on or about November 1, 2013.

418. Additionally, Defendants are equitably estopped, by virtue of their misconduct, from asserting that Plaintiffs' claims are time-barred.

XVI. CAUSES OF ACTION

COUNT ONE

(VIOLATION OF SECTION 10(b) OF THE EXCHANGE ACT AND RULE 10b-5(B) PROMULGATED THEREUNDER)

419. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein. This claim is asserted against all Defendants.

420. During the Relevant Period, the Defendants named in this Count: (a) deceived the investing public, including Plaintiffs, as alleged herein; (b) artificially inflated and maintained the market prices of Merck securities; and (c) caused Plaintiffs to purchase or otherwise acquire Merck securities at artificially inflated prices.

421. The Defendants made untrue statements of material fact and/or omitted to state material facts necessary to make the statements made not misleading, and/or substantially participated in the creation of the alleged misrepresentations, which operated as a fraud and deceit upon Plaintiffs, in an effort to maintain artificially high market prices for Merck common stock in violation of Section 10(b) of the Exchange Act and Rule 10b5(b). Defendants

consistently made materially false and misleading statements and omitted to state material facts regarding the cardiovascular dangers that Vioxx posed during the Relevant Period, thus materially misrepresenting Vioxx's medical and commercial viability.

422. As a result of their making, and/or their substantial participation in the creation of, affirmative statements and reports to the investing public, the Defendants had a duty to promptly disseminate truthful information that would be material to investors in compliance with the integrated disclosure provisions of the SEC as embodied in SEC Regulation S-K (17 C.F.R. § 229.10, et seq.) and other SEC regulations, including accurate and truthful information with respect to the Company's operations and performance so that the market prices of the Company's publicly traded securities would be based on truthful, complete and accurate information. With regard to the efficacy and medical and commercial viability of Vioxx, Defendants consistently failed to perform this duty.

423. The Defendants, directly and indirectly, by use of the means and instrumentalities of interstate commerce and/or the mails, made, or substantially participated in the creation of, untrue statements of material facts and/or omitted to state material facts necessary in order to make the statements made about the Company and/or Vioxx, in light of the circumstances under which they were made, not misleading, as set forth herein.

424. The Defendants had actual knowledge of the misrepresentations and/or omissions of material fact set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them.

425. The facts alleged herein give rise to a strong inference that each of the Defendants acted with scienter. The Defendants' own internal information concerning Vioxx provided the Defendants with statistically significant material information indicating that Vioxx carried severe

cardiovascular and thrombotic risks, such that the medical and commercial viability of the drug, as well as the revenue stream associated with it, was consistently threatened during the Relevant Period. The Defendants knew or recklessly disregarded that the financial results publicly disseminated to investors during the Relevant Period were significantly impacted by sales of Vioxx all over the world and that this material source of Company revenues remained at risk because of the dangers that Vioxx posed to people taking the drug. Defendants knew and/or recklessly disregarded the facts available to them during the Relevant Period which indicated that Vioxx would eventually have to be removed from the market, or even that Vioxx should not have been marketed at all in the first place.

426. To prevent negative information concerning Vioxx from entering the marketplace, the Defendants directly and/or indirectly carried out a deliberate campaign to silence and/or "neutralize" Vioxx's critics, including those at educational institutions and in the print media. The Defendants carried out this deliberate scheme in order to protect the revenue source that Vioxx represented for Merck, and Defendants knew that Vioxx's sales results would be incorporated into Merck's quarterly and annual financial statements and publicly-disseminated reports to investors.

427. Each of the Defendants also had a strong motive to engage in the fraudulent scheme set forth herein. Maintaining a strong stock price was essential to Merck's ability to expand its markets as well as to maintain the artificially inflated value of each of the Individual Defendants' personal holdings of Merck shares. Notwithstanding these Defendants' knowledge that Vioxx continuously posed severe cardiovascular and thrombotic risks to patients taking the drug, the Defendants knowingly and/or recklessly failed to disclose such material risks. Disclosure of the true facts concerning Vioxx would have seriously hampered Merck's position

in the pharmaceuticals marketplace. In addition, bonuses available to the Individual Defendants were heavily dependent on meeting the ever growing financial targets set by Merck.

428. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Merck's securities was artificially inflated throughout the Relevant Period. In ignorance of the fact that the market price of Merck's publicly traded securities was artificially inflated, and relying directly or indirectly on the false and misleading statements made by the Defendants, or upon the integrity of the market in which such securities traded, and the truth of any representations made to appropriate agencies and to the investing public, at the times at which any statements were made, and/or on the omission of material adverse information that was known or with deliberate recklessness disregarded by the Defendants but not disclosed in public statements by Defendants, Plaintiffs purchased or acquired Merck's securities at artificially high prices and were damaged thereby.

429. At the time of said misrepresentations and omissions, Plaintiffs were ignorant of their falsity, and believed the false statements to be true. Had Plaintiffs known that Vioxx presented such severe cardiovascular and thrombotic risks, facts which were misrepresented and/or not disclosed by Defendants, Plaintiffs would not have purchased such securities or, if they had purchased such securities, they would not have done so at the artificially inflated prices that they paid.

430. Defendants' materially false and misleading statements and omissions of material fact as alleged herein caused Plaintiffs to suffer losses in connection with its investments in Merck securities. Merck's stock price, and the value of the securities held by Plaintiffs collapsed during the period following the withdrawal of Vioxx from the market. By October 29, 2004, the

disclosure of Merck's Vioxx-related fraud reduced the share price by more than $15.10 per share and caused a loss of market capitalization of more than $37 billion.

431. By reason of the foregoing, the Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5(b), promulgated thereunder and are liable to Plaintiffs for damages that it suffered in connection with its purchases of Merck securities during the Relevant Period.

COUNT TWO

(VIOLATION OF SECTION 10(b) OF THE EXCHANGE ACT AND RULE 10b-5(a) AND (c) PROMULGATED THEREUNDER)

432. Plaintiffs repeat and reallege each and every allegation contained in each of the foregoing paragraphs of this Complaint as if fully set forth herein. This claim is asserted against all Defendants.

433. This Count is brought solely and exclusively under the provisions of Rule 10b-5(a) and (c). Accordingly, Plaintiffs need not allege nor prove in this Count that any Defendant made any misrepresentations or omissions of material fact for which they may also be liable under Rule 10b-5(b) and/or any other provisions of law.

434. During the Relevant Period, the Defendants carried out a common plan, scheme, and unlawful course of conduct that was intended to and did: (i) deceive the investing public, including Plaintiffs; (ii) artificially inflate the market prices of Merck securities; and (iii) cause Plaintiffs to purchase Merck securities at artificially inflated prices.

435. In furtherance of this unlawful plan, scheme and course of conduct, the 10(b) Defendants employed devices, schemes and artifices to defraud and knowingly and/or recklessly engaged in acts, transactions, practices, and courses of business that operated as a fraud and

deceit upon Plaintiffs in connection with its purchases of Merck securities, in violation of Section 10(b) of the Exchange Act and Rule 10b-5(a) and (c) promulgated thereunder.

436. The Defendants' fraudulent devices, schemes, artifices and deceptive acts, practices, and course of business included the knowing and/or reckless suppression and concealment of information regarding Vioxx's dangers and the corresponding continuing threat to Vioxx's medical and commercial viability during the Relevant Period. The Defendants knowingly suppressed and concealed such information to distort the balance of facts available to Merck's investors that would be included in the Company's financial statements disseminated to investors during the Relevant Period.

437. Plaintiffs reasonably relied upon the integrity of the market in which Merck's securities traded.

438. During the Relevant Period, Plaintiffs were unaware of the Defendants' fraudulent scheme and unlawful course of conduct. Had Plaintiffs known of the Defendants' unlawful scheme and unlawful course of conduct, they would not have purchased Merck securities or if they had, they would not have purchased such securities at the artificially inflated prices that they paid for such securities.

439. As a direct and proximate result of the Defendants' scheme to defraud and such Defendants' unlawful course of conduct, Plaintiffs suffered damages in connection with their purchases of Merck securities during the Relevant Period.

440. By reason of the foregoing, the Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5(a) and (c) promulgated thereunder and are liable to Plaintiffs for damages that they suffered in connection with their purchases of Merck securities during the Relevant Period.

COUNT THREE

(VIOLATION OF SECTION 20(a) OF THE EXCHANGE ACT)

441. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein. This claim is asserted against the Individual Defendants.

442. The Individual Defendants acted as controlling persons of Merck within the meaning of Section 20(a) of the Exchange Act, as alleged herein. By virtue of their respective high-level positions, and active, direct, and substantial participation in and/or awareness of the day-to-day operations at Merck, each of the Individual Defendants named in this Count had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various public statements and SEC filings that Plaintiffs allege were false and misleading. The Individual Defendants were provided with, or had unlimited access to, copies of reports, clinical studies, press releases, public filings and other statements alleged herein to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or to cause the statements to be corrected.

443. In particular, these Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company, and, therefore, are presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

444. As set forth in the preceding paragraphs of this Complaint, Merck and the Individual Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5(a)-(c) promulgated thereunder.

445. By virtue of their positions as controlling persons, the Individual Defendants named in this Count are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of their wrongful conduct, Plaintiffs suffered damages in connection with their purchases of the Company's securities during the Relevant Period.

COUNT FOUR

(VIOLATIONS OF SECTION 10(b) AND 20A OF THE EXCHANGE ACT AND RULE 10b-5 PROMULGATED THEREUNDER FOR INSIDER TRADING)

446. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein. This claim is asserted against Defendants Gilmartin, Lewent, Frazier, Scolnick, and Anstice (the "Section 20A Defendants").

447. This Count is asserted by Plaintiffs AEGON, KIA, KIO, and Transamerica (collectively, the "Section 20A Plaintiffs") pursuant to Section 20A of the Exchange Act.

448. As illustrated in Appendix A, attached hereto, contemporaneously with the Section 20A Defendants' insider sales of Merck common stock on dates identified in the table, the Section 20A Plaintiffs purchased shares of Merck common stock on a national securities exchange while the Section 20A Defendants possessed material adverse nonpublic information concerning Vioxx's cardiovascular risks and commercial viability which said Defendants failed to disclose in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, as more fully alleged in Counts One and Two above.

449. The Section 20A Plaintiffs have been damaged as a result of the Section 20A Defendants' violations of the Exchange Act as alleged herein.

450. By reason of their violations of the Exchange Act alleged in this Complaint, the Section 20A Defendants are liable to the Section 20A Plaintiffs, who purchased shares of Merck common stock contemporaneously with these Defendants' sales of Merck common stock.

451. The Section 20A Plaintiffs seek disgorgement by the Section 20A Defendants of profits gained (or losses avoided) from these Defendants' transactions in Merck common stock contemporaneous with those of the Section 20A Plaintiffs.

XVII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

A. Awarding compensatory damages against all of the Defendants, jointly and severally, in favor of Plaintiffs and for all losses and damages suffered as a result of Defendants' wrongdoing alleged herein, in an amount to be determined at trial, together with interest thereon;

B. Awarding Plaintiffs their reasonable costs and expenses incurred in this action, including a reasonable allowance of fees for Plaintiffs' attorneys and experts; and

C. Awarding Plaintiffs such other and further relief as the Court may deem just and proper.

XVIII. JURY DEMAND

Plaintiffs demand a trial by jury as to all issues so triable.

Dated: January 23, 2015

SAIBER LLC

BY: /s/ Marc E. Wolin

Jeffrey W. Lorell
Marc E. Wolin
18 Columbia Turnpike Suite 200
Florham Park, NJ 07932
Telephone: (973) 622-3333

Jay W. Eisenhofer
Geoffrey C. Jarvis
Jeff A. Almeida
Deborah A. Elman
Robert D. Gerson
GRANT & EISENHOFER P.A.
485 Lexington Avenue, 29th Floor
New York, NY 10017
Telephone: (646) 722-8500

Alexander Reus
DIAZ REUS ROLFF & TARG LLP
340 West Flagler Street., Second Floor
Miami, FL 33130
Telephone: (786) 235-5000

Attorneys for Plaintiffs

APPENDIX A

Plaintiff	***Plaintiff's Date(s)/Transaction(s)***	***Defendant***	***Defendant's Date(s)/Transaction(s)***
AEGON	2/4/2004 – Purchased 282,000 shares	Frazier	2/4/2004 – Sold 25,260 shares
KIA	10/25/2000 – Purchased 17,500 shares	Lewent	10/25/2000 – Sold 33,600 shares
		Scolnick	10/25/2000 – Sold 381,200 shares
KIA	11/1/2000 – Purchased 25,000 shares	Anstice	11/1/2000 – Sold 67,600 shares
KIA	5/6/2003 – Purchased 29,500 shares	Anstice	5/6/2003 – Sold 60,000 shares
KIO	8/1/2000 – Purchased 200,000 shares	Anstice	8/1/2000 – Sold 16,590 shares
KIO	2/2/2004 – Purchased 350,000 shares	Gilmartin	2/2/2004 – Sold 639,200 shares
KIO	8/4/2004 – Purchased 978 shares	Anstice	8/4/2004 – Sold 87,699 shares
Transamerica	7/27/2000 – Purchased 532 shares	Lewent	7/27/2000 – Sold 20,000 shares
Transamerica	7/28/2000 – Purchased 500 shares	Anstice	7/28/2000 – Sold 5,530 shares
Transamerica	10/25/2000 – Purchased 30,200 shares	Lewent	10/25/2000 – Sold 33,600 shares
		Scolnick	10/25/2000 – Sold 381,200 shares
Transamerica	10/26/2000 – Purchased 43,500 shares	Anstice	10/26/2000 – Sold 134,600 shares
Transamerica	11/1/2000 – Purchased 2,234 shares	Anstice	11/1/2000 – Sold 67,600 shares
Transamerica	7/26/2001 – Purchased 36,285 shares	Lewent	7/26/2001 – Sold 20,000 shares
Transamerica	5/1/2002 – Purchased 150,954 shares	Lewent	5/1/2002 – Sold 20,000 shares
Transamerica	8/7/2002 – Purchased 11,250 shares	Frazier	8/7/2002 – Sold 4,300 shares

Transamerica	2/11/2003 – Purchased 26,412 shares	Frazier	2/11/2003 – Sold 4,740 shares
		Lewent	2/11/2003 – Sold 25,000 shares
Transamerica	4/30/2003 – Purchased 156,800 shares	Lewent	4/30/2003 – Sold 25,600 shares
Transamerica	5/6/2003 – Purchased 10,000 shares	Anstice	5/6/2003 – Sold 60,000 shares
Transamerica	4/29/2004 – Purchased 400 shares	Anstice	4/29/2004 – Sold 60,000 shares